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Exhibit 1

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September 14, 2021

VIA E-MAIL

Ms. Nora Stoner
Office of Chemical Safety and Pollution Prevention
Office of Program Support
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460
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Re: Response to Bayer's Petition to Deny Sharda's Applications to Register Technical Prothioconazole Technical Product

Dear Ms. Stoner:

This letter constitutes the Response of Sharda Cropchem Ltd. ("Sharda") to Bayer CropScience's ("Bayer's") Petition to Deny the selective method application for a technical prothioconazole registration submitted by Sharda. In its original Petition, Bayer asserted that Sharda failed to cite and offer to pay compensation for 31 studies or other items it argued are required to support a technical prothioconazole registration. In a revised and corrected data list Bayer submitted on September 7, 2021, however, Bayer withdrew its request with respect to two of the 31 items.

In the course of its review, Sharda identified a few errors or omissions in its data matrix and associated offer to pay to Bayer. As a result, Sharda will agree to cite and offer to pay for five of the 29 data or other items remaining at issue: MRIDs 46923601, 50917601, 50917602, 47002601 and 47277008.

Bayer's inclusion of the balance of the studies and other items in its Petition reflects an attempt to expand the scope of what must be cited under FIFRA beyond data that are required to satisfy the current data requirements applicable to Sharda's registration application. Bayer's arguments ignore that a purpose of the selective method of data citation used by Sharda is to permit follow-on applicants to support their registrations with only the minimum data set required. Under FIFRA and its regulations, Sharda cannot be compelled to cite duplicative data. Similarly, Bayer ignores the clear distinction that EPA has repeatedly recognized between data that are required to satisfy data requirements which may be subject to compensation under FIFRA, and data that EPA may review for various scientific regulatory purposes which does not trigger a compensation obligation. Finally, Bayer's Petition seeks to require Sharda to cite a category of non-data items that fall well outside the scope of FIFRA *data* reliance obligations and requirements and that also are irrelevant to the *technical* prothioconazole registration sought by Sharda. As such, Bayer's Petition is without merit and should be denied.

Legal Background

Sharda used the selective method to satisfy the data requirements applicable to its product registration. As EPA noted in the Preamble to the Final Rule promulgating its data reliance regulations,[1] the selective method, in contrast to the cite-all method, enables an applicant to cite and offer to pay compensation for the "minimum data set" required to support registration of the applicant's product. 49 Fed. Reg. at 30893. Under the selective method, the applicant first must list each data (or "guideline") requirement applicable to its proposed product in its data matrix. 40 C.F.R. § 152.90(a).[2] The applicant then must demonstrate compliance with each listed data requirement through one of several methods, such as citation to a specific study or studies that satisfy the requirement (the "straight" selective method), or citation to all data pertinent to the requirement (the "cite-all option" under the selective method). *Id.* § 152.90(b).

As EPA has indicated, it created the selective method in response to the decision in *NACA v. EPA*, 554 F. Supp. 1209 (D.D.C. 1983), which rejected EPA's prior interpretation of FIFRA § 3(c)(1)(F) as requiring a follow-on applicant to cite *all* "data which the Agency might review or use in deciding whether to register his product, *i.e.*, all relevant data in the Agency's files." 49 Fed. Reg. at 30885. EPA explained that "[a]fter reviewing the statute in detail in light of the *NACA* decision, the Agency concluded … that there is an *important distinction* in the statute between (1) EPA review under FIFRA § 3(c)(1)([F]) to determine whether the applicant has satisfied the requirements that specify how an application must be supported by submission or citation for data, and (2) EPA review of data to determine whether to approve a properly supported application on risk/benefit grounds." *Id.* at 30887 (emphasis added); *see also id. n.3* (noting that the *NACA* court rejected EPA's previous interpretation that these two functions are "indistinguishable"). Thus, the Agency must engage in "two separate data review functions" in determining whether a proposed pesticide meets the registration standards in FIFRA § 3(c)(5). *Id.* at 30887-88. The first data review requires the Agency to determine whether the applicant has cited or submitted sufficient data to satisfy applicable data requirements to meet the standard in § 3(c)(5)(B). *Id.* at 30887. The second data review function requires EPA to consider any and all available data to determine whether the pesticide meets the risk/benefit criteria set forth in § 3(c)(5)(C) and (D). *Id.* at 30887-88, 30902. Critically, whereas EPA's consideration of data in the first review is governed by FIFRA's data compensation provisions, its consideration of the

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[1] 49 Fed. Reg. 30884 (Aug. 1, 1984).

[2] FIFRA § 3(c)(2)(A) requires EPA to publish "guidelines specifying the kinds of information which will be required to support [a] registration … and shall revise such regulations from time to time." EPA has done so by promulgating the "guideline" requirements in Part 158. On a case by case basis, EPA may conclude that the data specified under Part 158 are not sufficient to support the application. In such instances, pursuant to 40 C.F.R. § 158.75, EPA may require the applicant to submit specified additional data to support its application; alternatively, pursuant to FIFRA § 3(c)(7), EPA may condition approval of the registration on the subsequent submission of additional required data. If, after an original registration is granted – and particularly after there are also one or more follow-on registrants of the same pesticide – EPA later "determines that additional data are required," then FIFRA § 3(c)(2)(B) requires EPA to issue a data call-in ("DCI") to "all existing registrants of the pesticide" notifying them of the additional data requirements and setting deadlines for the submission of the required additional data.

broader universe of data to make the risk/benefit determinations required by subparagraphs (C) and (D) is not. *Id.*

EPA has repeatedly affirmed this "important distinction" in regulatory decisions, letters, and other Agency pronouncements. For example, in its April 11, 2000 letter decision rejecting a petition to deny filed by submitters of permethrin data, the Agency explained:

> Although EPA necessarily takes into account all relevant information available to the Agency when evaluating an application for a particular use of a pesticide, it does not follow that an applicant must offer to pay compensation for all such data. There is an ***important distinction*** between EPA review of data that an applicant must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(F), and EPA review of data for other scientific purposes ….

Letter Decision at 3-4 (emphasis added) (Exh. 1). The Agency cited page 30888 of the Preamble to its August 1, 1984 Final Rule in support. *Id.* at 4.

Similarly, in its March 21, 2011 letter decision rejecting Bayer's petition to deny or cancel certain imidacloprid registrations sought or held by Ensystex, EPA stated:

> Bayer also asserts that because Ensystex IV's application does not cite to or contain all the data necessary for registration, EPA does not have available to it data necessary to make the required [no unreasonable risk] finding[s] under FIFRA. Not so. *It is well established that for purposes of making its risk/benefit determination, EPA is not limited to data cited or provided by the applicant.*

Letter Decision at 9 n.5 (emphasis added) (Exh. 2). Again, EPA cited the Preamble to its August 1, 1984 Final Rule in support of this ruling. *Id.*

EPA's statutory reading that its consideration of data in making risk assessments concerning a pesticide does not, in itself, render the data a "data requirement" and subject to FIFRA's compensation provisions has also been affirmed in Agency letters to the industry. One example is EPA's June 19, 2001 letter responding to an inquiry from the Spray Drift Task Force ("SDTF") as to whether EPA's use of SDTF data in risk assessments for particular pesticides renders those data compensable for registrants of those pesticides. EPA advised:

> [A]n applicant is obligated to submit or cite all data necessary to satisfy EPA data requirements; applicants are not required to submit or cite all data that EPA may evaluate for the purpose of determining whether the pesticide satisfies the FIFRA unreasonable adverse effects standard or the FFDCA section 408 safety standard…. Accordingly, the critical inquiry in determining whether a given data submitter such as the SDTF is entitled to an offer of compensation is whether an applicant must rely on the submitter's data to satisfy Agency *data requirements*.

Letter Decision at 1-2 (emphasis added) (Exh. 3).

Another example is EPA's February 11, 2014 letter responding to an inquiry from the Generic Residential Exposure Task Force ("GRETF"), which was formed to develop data required by a DCI concerning pyrethroids, in lieu of joining the existing Residential Exposure Joint Venture ("REJV"). The GRETF requested confirmation that EPA's use of REJV data in risk assessments for individual pyrethroids while GRETF's data were being generated would not trigger compensation obligations. EPA agreed, explaining:

> You are correct that EPA's consideration of data in making a registration review or registration determination does not by itself compel submission or citation of data. *EPA must first require those data*.... [I]f GRETF members choose to satisfy registration review data needs for pyrethroids through submission of their own data, and those data meet EPA requirements, GRETF is not required to cite other data submitted, including data generated by the ... [REJV], even if EPA uses the REJV data in conducting its risk assessment.

Letter Decision at 1 (emphasis added) (Exh. 4).

Particularly relevant here is the Agency's discussion in the Preamble to its August 9, 2006 Final Rule promulgating regulations implementing the Registration Review process in FIFRA § 3(g). 71 Fed. Reg. 45720. There, EPA addressed the compensation status of so-called "voluntarily submitted" data, that is, data that are submitted during the Registration Review process, not to satisfy a DCI or address a data requirement applicable to a pending registration application, but to provide additional information to assist the Agency in conducting risk assessments for the pesticide. EPA affirmed that:

> [i]f a company submits data or information to the docket voluntarily (as opposed to providing these data or information in response to a DCI), such data are not 'required' data eligible for protection under the statute.

Id. at 45723. EPA added that if the Agency determines that it "must rely" on an item of "voluntarily submitted" data to support the continued registration of the pesticide – which EPA called a "compensable event" – the Agency will notify all registrants, either in a DCI or in a registration review decision document, that the data are now required and that other registrants then will have the opportunity to cite and offer to pay for the data, or to submit data to satisfy the new data requirement. *Id.*

The authorities reviewed above make clear that Bayer's reading of the scope of EPA "data requirements" is greatly overbroad. Data that do not correspond to a data requirement imposed by EPA do not become "data requirements" merely because EPA may want to use them, or has used them, in a risk assessment. To the contrary, EPA has repeatedly stated that its use of data in risk assessments does not, by itself, render the data "required" and compensable. Rather, such data are eligible for compensation only if and when EPA subsequently determines that it "must rely" on such non-guideline data to support the registration or continued registration of a pesticide. Furthermore, if and when EPA makes such a determination, it must then notify all other registrants of this "compensable event" and afford them the opportunity to exercise their

statutory right either to cite and offer to pay for the newly "required" data, *or* to submit their own data to satisfy the new data requirement. 71 Fed. Reg. at 45723.

The Data and other Items at Issue in Bayer's Petition

The eight categories of data and other items that are the subject of Bayer's Petition are addressed below.

1. Pollinator Data (7 studies)

EPA issued a data call-in for prothioconazole dated July 24, 2017, GDCI-113961-1613 ("2017 DCI"). *See* Bayer Pet., Exh. C. The 2017 DCI required the following pollinator data:

SS-1253	Larval honeybee chronic oral toxicity
SS-1254	Adult honeybee chronic oral toxicity
SS-1256	Adult oral toxicity-honeybee adult
SS-1257	Acute oral toxicity-honeybee larvae

Id. In addition, the 2017 DCI noted that EPA would determine if a Tier II study concerning field trials of residues in pollen and nectar (SS-1316) based on the results of the Tier I studies above. *Id.* To date, the regulatory record does not indicate that EPA has required a Tier II study.

Sharda addressed the requirements for SS-1253, SS-1254, SS-1256 and SS-1257 imposed by the 2017 DCI by citing (and offering to pay for) MRIDs 50633902, 50633903, 50546502 and 50546503. These studies fully satisfy the 2017 DCI's requirements for pollinator data.

With the exception of one study (MRID 50546501) that appears duplicative of another study Sharda cited (MRID 50726801), the pollinator studies in Bayer's Petition were generated prior to the 2017 DCI. These pre-DCI studies appear to be studies Bayer conducted for registration in Europe and submitted to EPA in 2018. As a general proposition and in certain cases, EPA may accept studies conducted to support a European registration to satisfy an EPA-imposed data requirement. These specific studies, however, do not correspond to a data requirement imposed by the 2017 DCI.

Bayer implicitly acknowledges that the 2017 DCI does not require those additional pollinator studies and argues, instead, that EPA "relied" on them in its Draft Ecological Risk Assessment for prothioconazole so Sharda should be required to cite them. Bayer Pet. at 8. Of course, in the Draft Ecological Risk Assessment for prothioconazole, EPA characterizes only one of the studies as acceptable; the balance are either supplemental or still "under review." *See* Bayer Pet., Exh. D.

The more important – and dispositive – point is that Bayer's argument ignores the "important distinction … between (1) EPA review under FIFRA § 3(c)(1)([F]) to determine

whether the applicant has satisfied the requirements that specify how an application must be supported by submission or citation for data, and (2) EPA review of data to determine whether to approve a properly supported application on risk/benefit grounds." 49 Fed. Reg. at 30887. As demonstrated above, EPA may consider any and all available data to determine whether the pesticide meets the risk/benefit criteria set forth in § 3(c)(5)(C) and (D). *Id.* at 30887-88, 30902. That assessment is wholly separate from EPA's determination of whether an applicant has cited sufficient data to satisfy applicable data requirements to meet the registration standard in FIFRA § 3(c)(5)(B). *Id.* at 30887. EPA's consideration of a study in its risk/benefit determination does not trigger FIFRA's data compensation requirements; compensation is required only if EPA considers data to satisfy an applicable data requirement. FIFRA § 3(c)(1)(F)(iii); *see, e.g.,* EPA Letter Decision at 3-4 (Exh. 1) ("There is an important distinction between EPA review of data that an applicant must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(F), and EPA review of data for other scientific purposes").

Further, EPA has not determined that the additional pollinator data claimed by Bayer are required, either in the data requirements imposed by the 2017 DCI or through other procedures mandated by FIFRA. These additional pollinator data do not, for example, correspond to the four types of pollinator studies required by the 2017 DCI. Bayer Pet., Exh. C (2017 DCI). As noted, there is another route by which EPA may make a determination that data submitted during Registration Review outside the requirements of a DCI are now required. That is a Registration Review decision document wherein EPA makes a determination that a "compensable event" has occurred such that additional studies submitted to EPA outside a DCI requirement now will be required. *See* 71 Fed. Reg. at 45723 (data submitted to EPA outside a DCI requirement "are not 'required' data eligible for protection"; if EPA later makes a determination that it "must rely" on them, it "will notify all registrants, either in a DCI or in a registration review decision document, that the data are now required and that other registrants then will have the opportunity to cite and offer to pay for the data, or to submit data"). No such determination with respect to the additional pollinator studies has been made, and Bayer cannot contend otherwise. Indeed, the regulatory record indicates that a number of the pollinator studies claimed by Bayer remain "under review" by EPA. *See* Bayer Pet., Exh. D at 7 ("New data have been submitted in support of Registration Review including acute and chronic toxicity studies on … terrestrial invertebrates…. While some of the data have completed reviews and are used to assess risk in this DRA, other studies that do not impact this assessment based on a preliminary review of the results are still under review and not included here."); *id.* at 34-35, 131 (MRIDs 50489204, 50489205, 50521803 "under review").

Turning to the specific pollinator studies Bayer contends Sharda should cite, the studies are not required for the following reasons:

50489203 – This is a 10-day honeybee adult chronic study completed in 2015, approximately two years prior to the 2017 DCI. Sharda cited a more recent 10-day honeybee adult chronic study completed after the 2017 DCI – MRID 50546503 – which fully addresses the requirement for SS-1254. Even if MRID 50489203 also addressed that same requirement, the selective method expressly permits Sharda to avoid the need to cite duplicative studies, as explained above.

50489204 – This study also pre-dates the 2017 DCI, concerns semi field testing for pollinators - tunnel or colony feeding studies (SS-1342). The 2017 DCI does not require such a study and EPA has not determined that a "compensable event" has occurred with respect to MRID 50489204. To the contrary, not only is there an absence of a finding in the regulatory record that EPA determined the study is required to support the registration of prothioconazole, EPA has not even completed its review of it. *See* Bayer Pet., Exh. D. at 34. Accordingly, Sharda is not required to cite it.

50489205 – This 2014 foreign chronic dietary exposure study also pre-dates the 2017 DCI and does not address any of the pollinator study data requirements required by the DCI: SS-1253, SS-1254, SS-1256 or SS-1257. Further, the regulatory record does not show that EPA has determined the study is required to support the registration of prothioconazole, and it remains "under review" by EPA. Bayer Pet., Exh. D. at 34, 131. Accordingly, Sharda is not required to cite it.

50521801 and 50521802 – These 2015 and 2016 studies concern acute exposure - acute contact LD5O, and do not address SS-1253, SS-1254, SS-1256 or SS-1257 which are the pollinator studies required by the 2017 DCI. In addition to not being required by the 2017 DCI, there has been no finding that by EPA that the studies are required to support the registration of prothioconazole.

50521803 – This 2003 study concerns subacute or subchronic field exposure. It does not address SS-1253, SS-1254, SS-1256 or SS-1257, which are the pollinator studies required by the 2017 DCI. The regulatory record also indicates that study remains under review, and contains no finding that it is required to support the registration of prothioconazole. Bayer Pet., Exh. D at 34, 131.

50546501 – According to NPIRS, this study bears the same project number and a similar title as a more recent study that Sharda did cite (MRID 50726801). As addressed above, Sharda is not required to cite duplicative studies. Sharda addressed the requirement in the 2017 by citing MRID 50726801, so citation of MRID 50546501 is not required.

2. Environmental Fate Data (2 studies)

Sharda's application cites MRIDs 46246507, 46246511, 46246512, 46246515 and 46246516 to address the requirements for aerobic soil and anaerobic aquatic metabolism studies. Based on further analysis, Sharda withdraws its citation of those studies and will agree to cite instead the two environmental fate studies in Bayer's Petition: MRIDs 50917601 and 50917602.

3. Toxicology Data (1 study)

Sharda inadvertently omitted MRID 46923601, and agrees to cite it.

4. Ecological Effects Data (1 study)

Bayer seeks to require Sharda to cite a 2007 study concerning life cycle testing for freshwater invertebrates, MRID 47626901. However, EPA classified this study as supplemental and the 2017 DCI required submission of another study. As such, MRID 47626901 does not satisfy the data requirement and Sharda is not required to cite it.

Bayer also contends Sharda should cite MRID 47626901 because, Bayer asserts, EPA "relied" upon it on its Draft Ecological Risk Assessment. Bayer Pet. at 10. Putting aside the fact that the references to the study in that Risk Assessment are limited to identifying its existence and classifying it as supplemental (Bayer Pet., Exh. D), this argument has no more merit than it does when Bayer makes it with respect to pollinator data, as discussed above. EPA repeatedly has confirmed that its consideration of a study in a risk assessment does not make that data required for purposes of satisfying the applicable data requirements.

5. Human Exposure Data (1 study)

Sharda inadvertently omitted MRID 47002601, and agrees to cite it.

6. Residue Chemistry – Analytical Method – Storage Stability (1 study)

Bayer seeks to require Sharda to cite MRID 48938301. EPA required Bayer to submit this study as a condition of its registration in 2012. However, there is no basis to show this is a current data requirement that Sharda must address. In that regard, EPA's regulations reflect the obvious fact that science and data requirements may evolve and change over time and a follow-on registrant is not required to satisfy all data requirements the original registrant addressed if EPA no longer imposes them. *See e.g.,* 40 C.F.R. § 152.86(d)(2)(ii) (referencing a follow-on applicant's obligation to satisfy "data requirements in effect on the date EPA approves the applicant's present application"); 40 C.F.R. § 152.90 (referencing the data requirements that apply to the follow-on applicant's product).

7. Residue Chemistry – Magnitude of the Residue Studies

Bayer seeks to require Sharda to cite nine residue studies. Of these, Sharda agrees to cite MRID 47277008. The remaining studies are not relevant to Sharda's proposed registration for the following reasons:

48516202, 48516203, 48516204, 48516205, 48024903, 48024904 – These studies were conducted by Bayer in Europe for European registration. EPA's residue chemistry guideline for crop field trials, 860.1500, requires that they be conducted in the United States, with the United States' soils and under the United States' weather conditions. As such, the foreign residue studies that are the subject of Bayer's Petition do not satisfy the data requirement and Sharda is not required to cite them.

49281501 – This is data related to a prothioconazole+trifloxystrobin mixture on corn. First, this data is not relevant because Sharda is not proposing to register a prothioconazole+

trifloxystrobin mixture product. Second, Sharda cited MRIDs 47521901, 47521903 and 48116901 to address EPA's requirement for residue data on corn for the foliar and seed treatment uses that Sharda is proposing to register on a prothioconazole (only) product. Sharda is not required to cite MRID 49281501.

8. Directions for Use Items

Finally, Bayer's Petition absurdly requests that EPA require Sharda to cite and offer to pay for seven[3] items it characterizes as "Directions for Use Data." Notably, the titles of the items Bayer seeks to require Sharda to cite reveal that they are petitions for a tolerance or tolerance exemption, not data submissions. There is no legal merit to Bayer's contention that tolerance petitions constitute "data" that Sharda should be required to cite for its technical prothioconazole registration. Bayer Pet. at 14. Even Bayer's own submissions do not support the position it now takes.

First, as Bayer concedes, the Directions for Use necessary requires submission of a *label*, not data. *See* OPPTS 860.1200(c)(1), *available at* https://nepis.epa.gov/Exe/ZyPDF.cgi/P100ICWX.PDF?Dockey=P100ICWX.PDF ("The directions for use are ordinarily contained in specimen labeling submitted concurrently for registration under FIFRA"); Bayer Pet. at 15 (conceding that Directions for Use are "submitted to EPA by Bayer in the form of specimen end-use labels that detail the required directions for use for each crop use"). Because EPA's Directions for Use requirement *does not* require the submission of data, it would not and cannot be satisfied by submission (or citation) of data. *Id.* Indeed, notwithstanding the new-found position Bayer now takes with respect to Sharda's registration application, Bayer has long recognized that EPA's requirement for Directions for Use is satisfied by submission of a label rather than submission/citation of data. Data matrices *submitted by Bayer* to support its own technical prothioconazole registration neither identify 860.1200 (or Directions for Use) as a Guideline or *data* requirement, nor do they cite any of the tolerance petitions Bayer now claims must be cited to support a prothioconazole registration. *See, e.g.,* Bayer Technical Prothioconazole Data Matrices (Exhs. 5-8).

Second, with respect to EPA's Directions for Use requirement that is satisfied by submission of a label, FIFRA's compensation rights and obligations apply to *data*, not to *labels* and any use directions they reflect. In that regard, FIFRA § 3(c)(1)(F) requires the submission of or citation to data and contains a compensation provision (FIFRA § 3(c)(1)(F)(iii)). In contrast, the provision of FIFRA requiring submission of a label – FIFRA § 3(c)(1)(C) – has no compensation provision. To accept Bayer's argument would dramatically expand FIFRA's data citation and compensation scheme by adding a right to compensation for *labels* that Congress did not see fit to include when it provided compensation for *data*.

Third, FIFRA requires that Sharda submit its *own* label containing Directions for Use. *See* FIFRA § 3(c)(1)(C) ("Each applicant for registration shall file a statement which includes …

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[3] Bayer's Petition identifies nine tolerance petitions as "Directions for Use Data," but by correspondence dated September 7, 2021 Bayer withdrew its Petition with respect to two Tolerance Petitions, MRIDs 48024800 and 48024900.

a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use). Accordingly, even putting aside the lack of citation and compensation provisions applicable to labels in FIFRA, the statute does not authorize EPA to rely on a Bayer's label in order to satisfy the requirement that Sharda submit one.

Fourth, Bayer also concedes that the Directions for Use on which its argument is based relate to the detailed instructions for using an *end use* pesticide product on a crop. *See* Bayer Pet. at 15 (asserting that so-called "DFU data" "were submitted to EPA by Bayer in the form of specimen *end-use* labels that detail the required directions for use for each crop") (emphasis added); *see also* Bayer Pet. Exhs. J-R (petitions submitted to establish tolerances for Bayer's end use prothioconazole products). Sharda's pending registration, however, is for a *technical* prothioconazole product. As EPA is aware, directions for use on Sharda's proposed technical prothioconazole label simply identify the crops to which end-use products formulated with its product may be applied; they do not provide directions for use of the product on those crops because it is not an end use product that can be applied. Bayer does not explain, much less demonstrate, that Sharda necessarily would have to conduct trials simply to determine the crops on which end use products formulated with Sharda's technical prothioconazole may be applied. In fact, the identity of the crops on which prothioconazole may lawfully be applied is in the public domain. Thus, even if Sharda were required to "cite data" to establish crops on which prothioconazole may be applied, Sharda could do so without "citing" Bayer's tolerance petitions.

Fifth, putting aside the fact that Bayer's argument concerning directions for use on end use labels is irrelevant to Sharda's proposed technical product, EPA expressly waived the requirement that applicants submit or cite data related to end use products' directions for use for most pesticides. In the lexicon of EPA, trials from which directions for use concerning uses, application, rates, timing and the like may be derived concern "product performance." As EPA explains:

> The term "product performance" refers to all aspects of a product's effectiveness and usefulness. Any evaluation of product performance is conducted in light of expressed and implied labeling claims or recommendations concerning pests, sites, methods of application, application equipment, dosage rates, timing and number of applications, use situations, nature and level of pest control, duration of pest control, compatibility with other chemicals, benefits and/or adverse effects of product use, compatibility of common practices associated with the sites, active ingredient status of chemicals in the formulation, and equipment.

EPA Product Performance Test Guidelines, OPPTS 810.1000, at 1, *available at* https://downloads.regulations.gov/EPA-HQ-OPPT-2009-0150-0002/content.pdf. The Test Guidelines define "effectiveness" as follows:

> Effectiveness refers to a product's ability to control the specific target pest or produce the specified plant or animal response when the product is applied in accordance with the label directions, precautions, and limitations of use. The term effectiveness, as used in this guideline, is synonymous with the term efficacy.

Id. at 4. EPA's Guidelines go on to "provide guidance concerning the methodology of efficacy testing and the content of test reports," while cautioning that "they *do not* independently establish any *data submittal requirements*." *Id.* at 5 (emphasis added). Critically, for example, EPA's Guidelines advise that the "test substance shall generally be the formulated product" – *i.e.*, end-use products, not technical products.

Just as EPA's Product Performance Test Guidelines establish that trials from which directions for use may be derived constitute product performance/efficacy tests, they also confirm that these tests are not required to be submitted to EPA in support of registration for agricultural herbicides. This is because "[t]he Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pests that may pose a threat to human health." EPA Product Performance Test Guidelines at 2. In fact, EPA waived the requirement to submit or cite product performance/efficacy data for pesticides such as prothioconazole more than 40 years ago, in 1979, in response to the 1978 FIFRA amendments. See 44 Fed. Reg. 27932, 27938-40 (May 11, 1979). EPA explained that the waiver would "reduce the amount of [Agency] resources devoted to reviewing product performance" data, noting that "the efficacy of agricultural pesticides can be effectively regulated by the marketplace." Id. at 27938. For those cases where marketplace regulation proved to be inadequate, EPA "reserve[d] the right to request submission of efficacy data" through data call-ins issued under FIFRA § 3(c)(2)(B). Id. at 27939.

EPA's waiver of the requirement for registrants to submit or cite efficacy/performance data currently appears in FIFRA's regulations at 40 C.F.R. pt. 158, Subpart E—Product Performance (CA54). In particular, § 158.400(e) n.1 states in pertinent part: "The Agency has waived all requirements to submit efficacy data unless the pesticide product bear a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user … or vertebrates … that may directly or indirectly transmit diseases to humans." Prothioconazole is an agricultural pesticide and is not used to control human heath pests (such as rodents, ticks, and pathogenic bacteria and viruses). As such, like most other pesticides, prothioconazole is subject to EPA's efficacy data waiver. 40 C.F.R. § 158.400(e) n.1. EPA has stated repeatedly that the efficacy of agricultural pesticides such as prothioconazole is "effectively regulated by the marketplace" and that, accordingly, it does not evaluate performance data for such products. *See, e.g.*, EPA Pesticide Registration Notice 96-4, "Label Statements Involving Product Efficacy and Potential for Harm to Property" *available at* https://www.epa.gov/pesticide-registration/prn-96-4-label-statements-involving-product-efficacy-and-potential-harm (EPA waiver for product performance data based on, inter alia, "the high level of knowledge concerning pesticidal efficacy that prevails in the agricultural community, the existence of means for communicating efficacy information to users, the organizational expertise of the Department of Agriculture, the extension services, and the universities, and the stake the industry has in marketing products that are efficacious") (citing S. Rep. 95-334, 95th Cong., 1st Sess. 20 (July 6, 1977)).

As EPA itself has recognized, the Agency's waiver of the requirement to submit product performance data relieves follow-on registrants from the requirement to compensate original registrants for those data, whether or not the data were ever submitted to the Agency. *See, e.g.,* 47 Fed. Reg. 57624, 57646 (Dec. 27, 1982) ("Much of the existing data are not compensable,

because ... efficacy data are no longer reviewed by the Agency"). Given EPA's broad waiver for product performance data, and EPA's explicit affirmation that such data are not eligible for compensation, it is not surprising that claims for compensation for such data have been repeatedly rejected in FIFRA cases.

In this regard, Bayer cherry picks two aberrant FIFRA arbitration decisions it contends support its position. But neither decision provides a legal basis for EPA to require a follow-on registrant to cite product performance data. This is because it is for the Agency – not arbitrators – to determine both the applicable data requirements and the data that satisfy them. *See, e.g.*, FIFRA § 3(c)(2)(A) (EPA establishes requirements for registration); 40 C.F.R. Part 158 (same). Putting that aside, Bayer also fails to disclose that the two decisions it cites are outliers that stand in contrast to a legion of decisions rejecting compensation claims for product performance data that go back to the first arbitration decision, *Stauffer Chem. Co. and PPG Industries, Inc.* There, the arbitrators noted:

> While … the original submitter may have been … required to obtain and submit expensive field test [i.e. efficacy] data whereas the follow-on registrant was not, the latter clearly is not responsible for any such discrepancy and should not be required to compensate the original data submitter for data that are no longer required by EPA for approval.

Award at 9-10 (excerpt provided in Exh. 9). Similarly, another arbitration panel found that EPA's efficacy waiver "reduced data submitters' rights by precluding compensation for efficacy data." *DuPont v. Griffin and Drexel*, Award at 17 (excerpt provided in Exh. 10). Arbitration panels also have ruled data owners are "not entitled as a matter of law to compensation under FIFRA for its costs to generate the product performance (or 'efficacy') data" included in its claim. *Abbott Labs. v. Agtrol Chem. Prods., Inc.*, Decision and Award at 2 (excerpt provided in Exh. 11). Similarly, in *GB Biosciences Corp. v. Nations Ag II, LLC*, the arbitrators issued a pre-hearing decision rejecting the data owner's claim for product performance studies allegedly used to support claims and directions for use on its labels. Mem. And Order at 4-6 (Nov. 19, 2001) (excerpt provided in excerpt provide in Exh. 12). The same result was reached in the *Monsanto v. Tacoma* arbitration, where Monsanto asserted that the directions for use instructions on its product labels, which were also on the end use labels of the follow-on, were derived from and supported by its "directions-for-use" field trials. Award at 29 (excerpt provided in Exh. 13). Monsanto argued that inasmuch as FIFRA requires the submission of a proposed label and that that label must be based on field test data, labeling addresses a data requirement. *Id.* The Tacoma panel rejected this (and other) arguments. *Id.* at 27. Other FIFRA arbitration decisions are in accord. The Agency should decline Bayer's invitation to add a new category of compensation available under FIFRA based on labels or other non-data items that do not correspond to a requirement satisfied by the submission of data.

* * *

WHEREFORE, for the foregoing reasons, Bayer's Petition should be denied.

Respectfully submitted,

James P. Rathvon
Cristen S. Rose

Attachments – Exhs. 1-13

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Exhibit 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 1 1 2000

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RE: Petitions to Deny

Dear Mr. Weinberg and Ms. Szmuszkovicz:

On June 21, 1999, the Agency received FMC Corp.'s (FMC's) "Petition to Deny Applications of United Phosphorus Inc. (UPI) for Registrations of Pesticides Containing the Active Ingredient Permethrin." On September 16, 1999, the Agency received Zeneca Inc.'s (Zeneca's) "Petition to Deny Applications of UPI for Registration of Pesticides Containing Permethrin as the Active Ingredient." FMC's and Zeneca's petitions were filed pursuant to 40 C.F.R. §152.99, which permits original data submitters to seek denial or cancellation of the registration of a product where the applicant for that product has failed to satisfy a data requirement the petitioner has fulfilled. Because the claims in FMC's and Zeneca's petitions mirror one another, the Agency has considered these petitions jointly.

On May 27, 1999, UPI submitted applications to register Permethrin Technical, Tengard MUP, and Tengard SFR. All three products contain permethrin as the sole active ingredient. In support of its applications for registration, UPI was required to comply with the data submission provisions of FIFRA section 3(c)(1)(F) and 40 C.F.R. Part 152, Subpart E – Procedures to Ensure the Protection of Data Submitters' Rights. In general, Subpart E requires applicants either to submit data regarding the various chemical properties, environmental effects, and toxic effects of the their products, or to rely on data previously submitted to the Agency by prior applicants.

Initially, UPI elected to submit its own product chemistry studies and to rely on EPA's selective method, *see* 40 C.F.R. §152.90, to support its registration applications. Subsequently, UPI amended its applications and relied on 40 C.F.R. §152.95, commonly referred to as the selective cite-all method, to support its registration applications. In relying on the selective cite-all method, UPI cited to all of the studies in the Agency's files pertinent to all of the data requirements for its products.

In addition to the submission of data or citation to data, UPI was required to offer to pay compensation to those persons who previously submitted data to the Agency upon which UPI's applications relied. UPI sent offer to pay letters dated May 26, 1999, to FMC and Zeneca. UPI's offer to pay was limited to FMC's and Zeneca's studies listed on UPI's selective-cite data matrices for Permethrin Technical, Tengard MUP, and Tengard SFR to the extent required by FIFRA section 3(c)(1)(F). When UPI amended its applications to rely on the selective cite-all method, its May 26, 1999, offer to pay letters to FMC and Zeneca were superseded by offer to pay letters dated January 11, 2000, and January 28, 2000. In the January 11, 2000, letters, UPI offered to pay compensation "with regard to UPI's Permethrin Technical and Tengard MUP applications, to the extent required by FIFRA §3(c)(1)(D) [sic] of [FIFRA] for the specific data requirements identified in the attached appendix." UPI split its originally-proposed end-use label for Tengard SFR into two separate labels–Tengard SFR and Tengard HG. In letters to Zeneca and FMC dated January 28, 2000, UPI offered to pay compensation with regard to these end-use products for the specific data requirements identified in the appendix attached to the letters. Finally, UPI submitted to the Agency a general offer to pay statement, as required by 40 C.F.R. §152.95(a), for any previously submitted data that may satisfy the guidelines listed in UPI's data matrix.

In a letter dated February 8, 2000, Zeneca "note[d] that the list provided by UPI [in its subsequent offer to pay letter] does not address several guidelines" satisfied by Zeneca and others, including "guideline numbers 122-1, 165-1, 165-2, 165-5, and seventeen additional ecotoxicology and spray drift submissions by members of the [Pyrethroid Working Group (PWG)]." However, as described below, the Agency has determined that UPI has satisfied the data requirements for registration.

The Agency's data requirements for registration are codified at 40 C.F.R. Part 158. In determining registration data requirements to satisfy FIFRA section 3(c)(1)(F), applicants are instructed to "[s]elect the general use pattern(s) that best covers the use pattern(s) specified on the pesticide product label" and to "[p]roceed down the appropriate general use pattern column in the [Data Requirement] table and note which tests . . . are required ("R"), conditionally required ("CR") or usually not required ("--- ")." 40 C.F.R. §158.100(b) and (c). Thus, under EPA regulations, data requirements are based on use patterns proposed by the applicant and not on the use patterns of existing registrants.

UPI's proposed labels are limited to non-food/feed, indoor/outdoor termiticide/insecticide use patterns. Guideline numbers 165-1, 165-2, and 165-5 are not listed as required data under 40 C.F.R. §158.290 for UPI's proposed use patterns. Guideline number 122-1 is required under 40 C.F.R. §158.540, but only if the pesticide is to be used in forests or natural grasslands or when other stipulated conditions are met. *See* 40 C.F.R. §158.540(b)(2). UPI's proposed uses do not meet these conditions. Similarly, because UPI's proposed labels are limited to non-crop uses and are not intended for major uses (e.g., cotton, corn soybeans, forests, etc.), UPI is not required to cite to the additional ecotoxicology and spray drift submissions by PWG members. UPI cited to all of the studies in the Agency's files pertinent to the following wildlife and aquatic organisms data guideline numbers: 71-1, 71-2, 71-4, 72-1, 72-2, 72-3, and 72-4. Although other aquatic and wildlife organisms data may be conditionally required, the potential exposure from UPI's intended use patterns do not warrant requiring such upper-tiered, life-cycle and field testing studies. *See* 40 C.F.R. § 158.490, notes 2, 6, and 8. Furthermore, UPI is not required to submit or cite to spray drift studies because UPI's proposed labels are not intended for aerial applications or broad area ground applications. *See* 40 C.F.R. §158.440(a), note (1).

All of the other claims[1] except for one in FMC's and Zeneca's petitions were rendered moot by UPI's amended applications and citation of all studies in the Agency's files pertinent to all of the data requirements for UPI's pesticide products. The only remaining issue for consideration is whether UPI must offer to pay compensation for or generate aggregate exposure data necessary for permethrin tolerance reassessment where permethrin is registered for both food and non-food uses but UPI's proposed uses are limited to non-food/feed uses and indoor/outdoor termiticide/insecticide uses. This is an issue of first impression before the Agency.

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), requires EPA to reassess all existing tolerances by making a safety determination consistent with section 408(b)(2). FFDCA §408(a). A tolerance is "safe" if there is "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all other exposures for which there is reliable information." FFDCA §408(b)(2)(A)(ii). When assessing the safety of pesticide chemical residues on food, the Agency must consider "available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances . . . ." FFDCA §408(b)(2)(D). Thus, in reviewing tolerance actions, the FFDCA requires EPA to assess aggregate exposure from multiple routes of exposure, including drinking water and other non-occupational uses. Congress imported this requirement into FIFRA by amending section 2(bb). Accordingly, in making unreasonable adverse effects determinations pursuant to FIFRA section 3(c)(5)(D), the Agency must consider whether there is "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard" under FFDCA section 408. FIFRA §§2(bb). Furthermore, the Agency stated in PR Notice 97-1 that it "intends to apply a similar standard to actions involving non-food use pesticides that may pose significant non-dietary risks to infants and children." EPA, Office of Pesticide Programs, Pesticide Registration (PR) Notice 97-1 (Jan. 31, 1997).

According to Zeneca, the FQPA's "new requirement to assess aggregate risk has eliminated much of the traditional distinction between requirements for food uses and non-food uses of pesticides that, like permethrin, are registered for both types of uses." Zeneca Petition at 13. Zeneca contends that "under the FQPA, the registrability of non-food uses of pesticides that are also registered for food uses is dependent in part upon data submitted to support the granting of a tolerance or exemption from the requirement of a tolerance." *Id.* Likewise, FMC maintains that "the continued authorization of non-food uses for those pesticides used for both food and non-food purposes rests, in substantial part, on data supporting tolerances and tolerance decisions." FMC Petition at 5. FFDCA section 408(i)(1) provides that data submitted to the Agency "in support of a tolerance or an exemption from a tolerance shall be entitled . . . to exclusive use and data compensation to the same extent" provided by FIFRA. Therefore, both FMC and Zeneca assert that UPI must offer to share in the costs of generating the data necessary for permethrin tolerance reassessment under the FQPA or generate the data itself.

Although EPA necessarily takes into account all relevant information available to the Agency when evaluating an application for a particular use of a pesticide, it does not follow that the

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[1]FMC's petition raised three claims: (1) UPI failed to properly document data gaps; (2) UPI failed to submit offers to pay compensation to the appropriate data submitters; and (3) UPI failed to include all required studies in its data matrices. Zeneca's petition raised two fundamental claims: (1) UPI failed to satisfy data requirements that have been satisfied by Zeneca and others; and (2) UPI failed to demonstrate how it will meet outstanding data requirements for registration under FIFRA and for tolerance reassessment under the FQPA.

applicant must offer to pay compensation for all such data. As discussed above, data requirements are based on use patterns proposed by the applicant and not on the use patterns of existing registrants. *See* 40 C.F.R. Part 158. There is an important distinction between EPA review of data that an applicant must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(F), and EPA review of data for other scientific purposes: "In the latter review, EPA may consider any relevant data without regard to who submitted the data, for what purpose, or when the data were submitted. In contrast, very specific limitations apply to the Agency's consideration of data in the first review." *See* EPA, Pesticide Registration and Classification Procedures; Procedures to Ensure Protection of Data Submitters' Rights, 49 Fed. Reg. 30884, 30888 (1984) (codified at 40 C.F.R. Parts 152 and 162).

Accordingly, the Agency may use data for whatever scientific purposes it deems necessary, including tolerance reassessment, provided that the Agency has adequately ensured the economic protections intended by FIFRA section 3(c)(1)(F). It is EPA's position that the current regulations continue to safeguard the economic protections provided by FIFRA section 3(c)(1)(F) by ensuring that each registrant bears responsibility for submitting or citing to data for the specific uses for which the product is intended. As the Agency explained in the 1984,

> FIFRA section 3(c)(1)(F)[2] clearly applies only to information required to be submitted with the application, not information used for any other purpose under FIFRA. The Agency may, and does, consider data for various scientific purposes--to determine risk/benefit consequences of use, to determine whether restrictions on use are necessary, to determine proper labeling for products, to determine whether to cancel or suspend a pesticide. In all these cases, the Agency uses data to arrive at its decision. But section 3(c)(1)(F) applies to Agency consideration of data for one purpose only--the Agency's determination under section 3(c)(5)(B) that "material required to be submitted [by section (3)(c)(1)] complies with the requirements of the Act." Having determined that the economic protections intended by section 3(c)(1)(F) have been adequately ensured, the Agency may subsequently use the data for whatever scientific purposes it deems necessary, by itself or together with other available information. It is the Agency's opinion that such use is not governed by section 3(c)(1)(F), and that consideration of any data for purposes other than sufficiency of an application under section 3(c)(5)(B) does not trigger the application of the exclusive use or compensation provisions of section 3(c)(1)(F) to that data.

49 Fed. Reg. at 30902.

Moreover, such a distinction is buttressed by the District Court for the District of Columbia's decision in *National Agricultural Chemicals Association v. U.S. Environmental Protection Agency*, 554 F. Supp. 1209 (D.D.C. 1983) (hereinafter "*NACA*"). In that case, the court rejected EPA's interpretation of FIFRA contained in the Agency's 1979 cite-all regulations, and held the 1979 regulations invalid insofar as they required an applicant to cite every study in the Agency's files relevant to the applicant's product. The district court enjoined EPA from requiring applicants to submit or cite more data than needed to meet the "statutory criteria for registration."

This distinction is further supported by congressional intent. Congress intended for the

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[2] After this statement was made in 1984, FIFRA was subsequently amended. Consequently, the provisions that appeared in section 3(c)(1)(D) in 1984 now appear in section 3(c)(1)(F). Therefore, 3(c)(1)(F) has been substituted for 3(c)(1)(D) throughout this quotation.

Agency to review data other than those submitted by applicants, as evidenced in several provisions of FIFRA. Sections 3(c)(5) and (7) require the Agency to determine that either the product and its uses will not cause unreasonable adverse effects on the environment, or that use of the product will not significantly increase the risk of unreasonable adverse effects on the environment. Under FIFRA section 2(bb), the term "unreasonable adverse effects on the environment" means:

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a).

This definition "clearly contemplates that the Agency will examine information beyond that which applicants are required to provide." 49 Fed. Reg. at 30888. Moreover, FIFRA section 3(c)(2)(A) requires that the Administrator make available to the public after registration "the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision." "Other scientific information," as the Agency has pointed out before, "clearly refers to information distinct from that submitted by the applicant." 49 Fed. Reg. at 30888.

In sum, requiring UPI to share in the costs of generating the data necessary for permethrin use patterns that have not been proposed by UPI would run contrary to current Agency regulations at 40 C.F.R. Part 158 and, as supported by *NACA* and congressional intent, is not mandated by FIFRA section 3(c)(1)(F). In passing FFDCA section 408 and amending FIFRA section 2(bb), the Agency does not believe that Congress intended to compel sweeping changes in the data compensation scheme that, in large measure, would render the current data tables in Part 158 meaningless and increase by considerable–in some instances geometric–proportions the obligations of applicants and EPA in satisfying FIFRA's data submission and application review requirements. UPI submitted or cited data in support of its applications based on its proposed use patterns. The Agency has determined that UPI's submissions satisfy the requirements of 40 C.F.R. Part 158 and that the economic protections intended by FIFRA section 3(c)(1)(F) have been adequately ensured. As discussed above, the Agency may subsequently use data, by itself or together with other available information, for whatever scientific purposes it deems necessary, including both adverse effects determinations and tolerance decisions. Therefore, FMC's and Zeneca's petitions to deny are denied.

Sincerely,

James J. Jones, Director
Registration Division

cc: James C. Wright, Esq.
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Exhibit 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CERTIFIED MAIL

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MAR 2 1 2011

James P. Rathvon
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Re: Petition of Bayer CropScience, LP to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc.

Dear Mr. Sachs and Mr. Rathvon:

This letter constitutes the response of the Environmental Protection Agency (EPA or Agency) to a petition filed by Bayer CropScience, LP (Bayer) dated September 8, 2009, to cancel all technical and end-use registrations for imidacloprid held by Ensystex III, Inc. and Ensystex IV, Inc. (together, Ensystex), and to deny any pending Ensystex applications for additional imidacloprid end-use products. EPA is in receipt of the following submissions:

1. Petition of Bayer to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc., September 8, 2009.

2. Response to Bayer's Petition to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc., November 9, 2009.

3. Reply in Support of Bayer's Petition to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc., November 20, 2009.

4. Surreply of Ensystex III, Inc. and Ensystex IV, Inc., February 2, 2010.

5. Reply in Support of Bayer's Petition to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc., July 15, 2010.

Background

On October 16, 2006, EPA issued a technical imidacloprid registration for "ENS-101" (EPA Reg. No. 82957-1) to Ensystex III, Inc. (Ensystex III). On January 31, 2007, EPA issued a second technical imidacloprid registration to Ensystex III "ENS-010A" (EPA Reg. No. 82957-4). In addition, EPA issued registrations to Ensystex III for two end-use product containing imidacloprid as the active ingredient:

(1) "Prothor WP" (EPA Reg. No. 82957-2), approved on February 12, 2007; and

(2) "Turfthor WP" (EPA Reg. No. 82957-3), approved on November 2, 2006.

In connection with the applications for these registrations, it is undisputed that Ensystex III submitted an "offer to pay" dated October 24, 2006. Specifically, the letter provides that Ensystex III's application uses the selective method of support as well as the "cite-all within selective method" for particular guideline studies.

Subsequently, EPA issued several imidacloprid end-use product registrations to Ensystex IV, Inc. (Ensystex IV):

(1) "Bithor SC GC" (EPA Reg. No. 83923-1), approved on February 12, 2007;

(2) "Bithor SC" (EPA Reg. No. 83923-2), approved on February 12, 2007;

(3) "Prothor SC 0.5" (EPA Reg. No. 83923-3), approved on March 6, 2007;

(4) "Prothor SC 2" (EPA Reg. No. 83923-4), approved on March 6, 2007; and

(5) "Turfthor 2F" (EPA Reg. No. 83923-5), approved on August 21, 2007.

It is undisputed that Ensystex IV submitted an "offer to pay" dated October 24, 2006 for Prothor SC 0.5, Prothor SC 2, Bithor SC, and Bithor SC GC. The letter informed Bayer that Ensystex IV intended to use the cite-all under selective method of data support to satisfy acute toxicity and efficacy data requirements only.

In addition, EPA issued two imidacloprid end-use product registrations to Ensystex IV on August 8, 2008:

(1) "Turfthor 2.5G" (EPA Reg. No. 83923-9); and

(2) "Turfthor 0.5G" (EPA Reg. No. 83923-10).

Again, it is undisputed that Ensystex IV submitted an "offer to pay" to Bayer dated April 11, 2008 in connection with these end-use products. The letter informed Bayer that Ensystex IV intended to use the cite-all under selective method of data support to satisfy acute toxicity data requirements only. Finally, Ensystex IV also submitted an "offer to pay" to Bayer dated June 11, 2008 for two end-use products identified as "Bithor G" and "Bithor G GC." The letter informed Bayer that Ensystex IV intended to use the cite-all under selective method of data support to satisfy acute toxicity and efficacy data requirements only.

The substance of Bayer's petition, however, has to do with data requirements for which Ensystex III has not made a valid offer to pay. Specifically, Bayer asserts that its petition is "based upon the fact that Ensystex has not offered to compensate Bayer for the use of at least 33 items of imidacloprid data that were prepared and submitted to EPA by Bayer, and that are necessary to fulfill ecological effects, toxicology and environmental fate data requirements pertinent to Ensystex's registrations for imidacloprid."[1] Petition at 2.

Timeliness

The regulatory procedures governing petitions by an original data submitter to deny or cancel a registration are found at 40 CFR § 152.99. Section 152.99(a)(1) applies where an applicant has offered to pay compensation to the original submitter of a study. Section 152.99(a)(2) applies where no offer to pay has been made. Bayer's petition is explicitly made pursuant to section 152.99(a)(2); namely, that Ensystex III and Ensystex IV failed to make an offer to pay to Bayer for required data, and that Ensystex III and Ensystex IV failed to otherwise satisfy those data requirements. Petition at 4. Petitions filed pursuant to section 152.99(a)(2) "must be filed within one year after the Agency makes public the issuance of the registration." 40 CFR § 152.99(b)(1).

Bayer argues that its petition is timely because EPA first publicized the issuance of the registration of Ensystex IV's Turfthor 2.5 G and Turfthor 0.5G end-use product through its Pesticide Product Information System (PPIS) on September 8, 2008. In addition, the one year limitations period had not yet begun to run with respect to "Bithor G" and "Bithor G GC" because those registrations appeared to still be pending at the time Bayer petitioned the Agency to deny those applications. However, Bayer offers no argument as to the timeliness of its petition with respect to the remaining Ensystex III or Ensystex IV registrations.

EPA agrees that the petition is timely with respect to Bayer's challenge to Ensystex IV's "Turfthor 2.5 G" and "Turfthor 0.5G" end-use product registrations as well as the "Bithor G" and "Bithor G GC" applications. However, it is clearly untimely with respect to registrations granted and made public prior to September 8, 2008. Accordingly, with respect to Ensystex III and its technical registrations, ENS-101 and ENS-010A, as well as its Prothor WP and Turfthor WP end-use registrations, Bayer's petition is **DENIED** as untimely. In addition, with respect to Ensystex IV and its Bithor SC GC, Bithor SC, Prothor SC 0.5, Prothor SC 2, and Turfthor 2F, Bayer's petition is **DENIED** as untimely.

Formulators' Exemption

With respect to the registrations that remain at issue (Ensystex IV's "Turfthor 2.5 G" and "Turfthor 0.5G" end-use product registrations and its "Bithor G" and "Bithor G GC" applications), Ensystex IV argues that its end-use products are formulated using registered technical imidacloprid purchased from Ensystex III. Accordingly, Ensystex IV argues that the remaining registrations qualify for the formulators' exemption.

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[1] Bayer has also asserted that it is entitled to petition EPA under the Administrative Procedures Act (APA), 5 U.S.C. § 555(b) and the Petition Clause of the First Amendment to the United States Constitution. Petition at 5. However, Bayer has only raised claims that are subject to the data compensation petition process in 40 CFR, subpart E—Procedures to Ensure Protection of Data Sumitters' Rights. Insomuch as Bayer has in fact submitted petitions under the APA and the Petition Clause of the First Amendment to the United States Constitution, it does not appear that there is any further relief EPA can or should grant pursuant to those authorities.

The formulators' exemption originates in section 3(c)(2)(D) of the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA), which provides:

> No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to –
>
> (i) submit or cite data pertaining to such purchased product, or
>
> (ii) offer to pay reasonable compensation otherwise required ... for the use of such data.

In addition, EPA has issued regulations governing the formulators' exemption at 40 CFR § 152.85.

Ensystex IV argues that since all 33 data items addressed in Bayer's petition pertain to Ensystex III's technical products, Ensystex IV has no obligation to cite or offer to pay for those data. Alternatively, Ensystex IV argues that 26 of the 33 data items included in Bayer's petition were originally submitted more than 15 years ago and are no longer eligible for compensation. With respect to the remaining data items, Ensystex IV further argues that none are required to support Ensystex III's technical registration, on which Enystex IV's end-use registrations are based.[2]

Bayer argues that the formulators' exemption does not excuse Ensystex IV from offering to pay for data that have not been satisfied by the technical product that it purchases. According to Bayer, the formulators' exemption cannot overcome database deficiencies in the technical product. In support of this proposition, Bayer relies on a 2003 data compensation decision in which EPA held that the formulators' exemption does not exempt a formulator from meeting data requirements applicable to use patterns that differ from those supported by the purchased registered pesticide from which the product is formulated. *See* EPA Petition Response: In re Petition of Chlorpropham Task Force to Cancel Registration of Dataplex, S.A., (November 4, 2003) (hereinafter "*Dataplex*").

In *Dataplex*, a company called Pin Nip, Inc. had previously registered technical chlorpropham. Subsequently, Dataplex S.A., a formulator proposing to utilize the Pin Nip technical as its source of active ingredient, applied for and was granted a registration for an end-use product, claiming it was similar to other registered products on the market and asserting that it was exempt from the requirements of submitting, or citing and paying compensation for, generic data to support the application for registration pursuant to the formulators' exemption because it would produce its product from a registered pesticide. Dataplex's end-use product, however, included certain use patterns in addition to those that were supported by the Pin Nip technical product registration. Because the Pin Nip technical product registration did not support those use patterns, EPA determined that the discrete data requirements pertaining to those uses were outside the scope of the formulators' exemption. In so doing, EPA concluded that reading its regulations to exempt products from all data requirements, regardless of differences between the uses and claims made for formulated products and the purchased manufacturing use product from which it is produced would be inconsistent with the purpose of the formulators' exemption and the data compensation scheme established in FIFRA. *Dataplex* at 5.

[2] Because Bayer's petition is being denied on other grounds, EPA does not reach Ensystex's alternative arguements.

In explaining that section 3(c)(2)(D)(i) only exempts formulators from data requirements "pertaining to [the] purchased product," EPA stated that "a formulator is exempt from data requirements only to the extent that those data requirements have been satisfied for the purchased pesticide product." *Id.* Bayer has seized upon this and other language to argue that *Dataplex* is not limited to situations where the technical registration was not registered for the uses on the end-use product (and, therefore, could not have satisfied the data requirements for those uses). Rather, Bayer asserts that *Dataplex* stands for the proposition that the formulators' exemption does not apply to any data deficiency, regardless of whether the technical or manufacturing use product is registered for the same uses as the reformulated product. In so doing, Bayer has taken this statement out of context and advocates an interpretation of *Dataplex* that is both overly broad and inconsistent with EPA regulations and the plain meaning of the statute.

Again, the issue in *Dataplex* was whether the formulators' exemption applied to data requirements for use patterns that were in addition to those for which the purchased technical product was registered. The statement in *Dataplex* that the "formulator is exempt from data requirements only to the extent that those data requirements have been satisfied for the purchased pesticide product" was made in the context of rejecting Dataplex's argument that it is of no consequence what uses a technical or manufacturing use product is registered for as long as the formulator uses a registered technical or manufacturing product to formulate a product that is similar to some other registered product. The question of whether Pin Nip had adequately satisfied the data requirements applicable to its technical registration was not at issue. Thus, EPA's statements in *Dataplex* with respect to satisfaction of data requirements were solely directed to the actual data requirements associated with uses for which the "purchased pesticide product" was registered (as opposed to a determination as to whether those requirements had been "satisfied" by the technical registrant).

Indeed, EPA's explanation in *Dataplex* clearly confines the discussion of satisfying data requirements to the determination that the formulators' exemption cannot exempt a formulator from data requirements related to uses not supported by the technical product. *See Dataplex* at 5, 6, & 7 ("Reading [the formulators' exemption] to exempt products from all data requirements, regardless of differences between the uses and claims made for formulated product and the purchased manufacturing use product from which it is produced would be inconsistent with [the formulators' exemption] and the data compensation scheme established ... [in] FIFRA"; "Thus, the formulator could not produce from the [Pin Nip Technical] an end use [sic] product for use patterns that are not fully supported by the [Pin Nip Technical] registration, unless the formulator submits or cites data to support the additional use patterns"; "Because the [Pin Nip Technical] registration does not support those use patterns, they are outside the scope of the formulators' exemption, and Dataplex is required to submit or cite data to support these use patterns"; Dataplex has not submitted or cited data to support use patterns...that are additional to those for which the [Pin Nip Technical] is registered").

Furthermore, as part of EPA's explanation of this statement in *Dataplex* concerning the extent to which formulators are exempt, EPA reiterated that it has been EPA's longstanding position that the registrant of an end-use product cannot ordinarily add uses that are not on the technical product label and for which there are different data requirements without citing or submitting additional data beyond that supporting the technical registration. *See* Pesticide Registrant Notices 94-1, 98-10, and 95-2. This is consistent with the language of the formulators' exemption, which exempts formulators who purchase a registered technical from the data requirements that pertain to the registered technical. In other words, if the formulator purchases a registered technical or manufacturing use product, the formulator is exempt from the data

requirements that were required of the registered technical or manufacturing use product purchased by the formulator (but only those data requirements). As discussed below, in this case, the formulator is exempt from those data requirements and the issue of data compensation with respect to those data requirements must be resolved between the original data submitter and the technical or manufacturing use product registrant. Thus, the relevant legal issue *Dataplex* resolved was that section 3(c)(2)(D) only exempts the formulator from those data requirements that were required of the registered technical or manufacturing use product purchased by the formulator. It did not address whether data submitters can effectively challenge the compliance status of a registered technical product through a petition to cancel an end-use product that utilizes that technical product as its source of active ingredient.

Bayer also places great significance on EPA's statements in *Dataplex* regarding Congressional intent and that, in certain circumstances, it would be "unreasonable to interpret section 3(c)(2(D) to allow formulators to avoid even paying once...." *Dataplex* at 5. In *Dataplex*, EPA noted that its decision was consistent with one of the rationales supporting the formulators' exemption; namely, that that formulators would pay data compensation to the extent such costs are incorporated into the price of the manufacturing use product. In this context, the Agency opined that nothing in FIFRA suggested that Congress intended formulators to rely on someone else's data without compensation.

A review of the legislative history surrounding adoption of the formulators' exemption indicates that while data compensation was a consideration, the primary purpose of section 3(c)(2)(D)was to simplify the registration of reformulated products, both for the Agency and for formulators. In fact, the legislative history of the 1978 amendments to FIFRA indicates that they were primarily designed to facilitate the implementation of major changes made to FIFRA in 1972 and to improve the operation of the federal pesticide registration program. (H.R. Rep. 95-663, at 1988 and 1990 (1977); S. Rep. 95-334, at 1 (1977)). The largest concern was that "the registration and reregistration process has ground to a virtual halt." (S. Rep. 95-334, at 3). One of the provisions included to improve EPA's ability to reach registration decisions more promptly was the formulators' exemption. The Senate Report described the provision in its section-by-section analysis as:

> "establish[ing] a simplified system for the registration of pesticides, and would exempt applicants who propose to purchase registered technical-grade or manufacturing-use pesticides for formulation into end-use products from submission of data pertaining to the safety of such purchased product, and from the obligation to offer to pay or pay compensation to the person from whom the pesticides was purchased under section 3(c)(1)(D) for use of data relating to the safety of the purchased product."

(S. Rep., 95-334, at 19).[3]

The legislative history shows that the emphasis was on allowing EPA to use a "generic" approach to pesticide registration, and "devote more attention to basic or technical material of these manufactures." (S. Rep. No. 95-334 at 27). The formulators' exemption codified this "generic" approach. In further explanation of the legislation, the House Report provides:

[3] Originally, the data compensation provision was codified at FIFRA section 3(c)(1)(D). Subsequent amendments to FIFRA caused the data compensation provision to be renumbered and it is now be codified at FIFRA section 3(c)(1)(F).

> Currently there is no differentiation in FIFRA between basic manufacturers and formulators. H.R. 8681 would obviate the need for formulators to furnish certain registration data by providing authority for "generic" registration. Formulators who buy registered basic pest control chemicals from another producer to formulate his purchased pesticide into an end-use product would not be required to submit data requirements as to the basic pest control chemical. Under the "generic" registration plan, detailed submission and evaluations of the basic chemical need not be repeated with each formulation. Registration actions would be based on the unique aspects of the particular formulation, applications will be simplified and formulators relieved of the need to offer to pay for the registration data except in the purchase price of the basic pest control chemical.

(H.R. Rep. No. 95-663, at 5). Further insight as to the purpose of the legislation can be found in testimony by the Administrator of EPA:

> As we testified last month, it has become increasingly clear that we are spending far too much time on individual end-use formulation applications, and that the whole structure for registration needs to be focused primarily on the chemicals themselves rather than thousands of individual applications for products containing mixtures of chemicals. Section 1 of our bill would facilitate that restructuring. We envision a system in which it is the technical material which becomes the focal point for registration, with the bulk of the safety data obtained from manufacturing-use, rather than end-use, registration. This would mean that the issues of compensation for the most expensive data—chronic feeding, environmental chemistry, fish and wildlife, and so forth—would be worked out among the registrants of technical products. The cost of that data *could* be included in the price for which the technical product sells. Thus, the formulator, *would in effect* be buying data rights along with the technical material, without having to go through the 3(c)(1)(D) procedures. Formulators might have to engage in 3(c)(1)(D) transactions for data specifically pertaining to the end-use formulation—if that data had been submitted by another formulator, for instance—but such transactions would be relatively simple. In other words, we see two sets of registrants who must settle up with one another: registrants of technical or manufacturing-use materials, and registrants of formulated products. We believe that the Act should specifically advocate this dichotomy and specify that formulators who purchase a registered pesticide product from another product need not submit data pertaining to the safety of the purchased product, as opposed to the safety of the formulated end-use products.

(H. R. Rep. No. 95-343(I) at 11 (1977)) (emphasis added). Thus, from a data compensation perspective, the focus of the formulators' exemption was to create a framework where data compensation "would be worked out among the registrants of technical products" and to protect

the formulator from duplicative payment for data development costs.

In *Dataplex*, however, the formulator was arguing that it was exempt from data requirements that were not the same as data requirements for the technical grade chemical used to formulate the end-use product (because the uses for which the technical product was registered were not the same as the uses for which the company in *Dataplex* was formulating its product). Consequently, there would be no opportunity for the issue of data compensation to be worked out among the original data submitter and the registrant of the technical or manufacturing use product pursuant to section 3(c)(1)(F) of FIFRA. In that case, there would be no market forces at work to pass through costs to the formulator. It was in this context that EPA concluded that it would be unreasonable "to allow formulators to avoid even paying once in certain circumstances." Again, EPA was merely emphasizing that the formulators' exemption only exempts the formulator from data requirements applicable to the registered technical product to the extent that the 3(c)(1)(F) procedures allowed for the original data submitter to be compensated. In other words, it would be unreasonable interpret the formulators' exemption such that it would completely circumvent the protection afforded original data submitters under section 3(c)(1)(F) to seek compensation for data from the registrant selling the technical or manufacturing product to the formulator.

Here, in contrast, the use patterns of the end-use products are not different from those that were purportedly supported by the technical registration. Thus, the predicate condition for the formulators' exemption has been met; namely, the formulator has purchased a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application, and the uses of the formulated product are not broader than those contemplated by the purchased technical product.[4] To the extent that the data requirements for the registered technical and formulator's end-use product are the same, the formulator is exempt from those data requirements. *See* S. Rep. No. 95-334 at 28. ("Specifically, formulators who purchase registered technical-grade chemicals to incorporate into end-use products would be exempted from data requirements on the technical-grade chemicals.").

The real heart of the issue here is Bayer's contention that Ensystex III did not make an offer to pay for data necessary to support its technical registration. Under the statutory framework established by Congress, to the extent that the data requirements of the reformulated end-use product are the same as the data requirements for the registered technical or manufacturing use registration, the end-use formulator does not need to cite to or provide data that pertaining to those same data requirements. Here, under the statutory framework, Bayer's recourse is limited to seeking data compensation for the data at issue from the technical registrant, not the end-use formulator. The fact that Bayer is time-barred from bringing a petition to cancel the technical registration for failure to make an offer to pay does not change the scope of the formulators' exemption. Bayer cannot now circumvent this bar through a collateral attack on Ensystex IV's end-use registrations by imputing a limitation on the formulators' exemption that is not supported by the text of the exemption or the legislative history. Accordingly, Bayer's petition with respect to Ensystex IV's remaining end-use product registrations as well as Ensystex IV's

[4] Bayer suggests that the rationale behind exempting formulators from 3(c)(1)(D) transactions with respect to generic data—that formulators pay for data through the purchase price of the product it is reformulating, is inapplicable when dealing with closely related companies. Nonetheless, Bayer does not contest that Ensystex III and Ensystex IV are distinct legal entities. Nor does Bayer argue that Ensystex IV is not "another producer" for purposes of the exemption.

"Bithor G" and "Bithor G GC" applications is **DENIED**.[5]

Sincerely,

Lois Rossi

Lois Rossi, Director
Registration Division

cc: Venus Eagle, RD
Andrew J. Simons, OGC

[5] Bayer also asserts that Ensystex IV cannot rely on the formulators' exemption to secure approval of registrations unless "there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7)." 40 CFR § 152.85(e). Bayer argues that because Ensystex IV's application does not cite to or contain all the data necessary for registration, EPA does not have available to it data necessary to make the required finding under FIFRA. Not so. It is well established that for purposes of making its risk/benefit determination, EPA is not limited to data cited or provided by the applicant. *See generally*, 49 Fed. Reg. 30884, 901-02 (August 1, 1984) (section 3(c)(1)(D) only applies to information required to be submitted, not for other purposes under FIFRA such as determining the risk benefit consequences of use). Indeed, EPA does not routinely reconsider the data supporting the technical registration each time a new end-use product is registered, just as EPA does not routinely reconsider the data underlying a registered product when a "me-too" application is filed.

Exhibit 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 19

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Charles A. O'Connor, III
Lawrence J. Joseph
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Dear Messrs. O'Connor and Joseph:

Thank you for your letter of October 3, 2000, to Mr. Jay Ellenberger and Ms. Michele Knorr of the Agency regarding use of Spray Drift Task Force data and the AgDRIFT model for registration and tolerance actions. In your letter you provide an opinion for use of these data and the model by member and non-member companies for these actions and ask the Agency to respond accordingly with its agreement or disagreement. We have given your letter full consideration and offer our response.

The Agency agrees with key elements of your characterization of the Spray Drift Task Force's (SDTF) spray drift data and of the AgDRIFT model and that EPA may not allow a non-member applicant or registrant to utilize compensable SDTF data to satisfy EPA data requirements unless that applicant or registrant has first offered to pay compensation to the SDTF. Further, EPA agrees that the CRADA in no way alters the SDTF's otherwise applicable compensation rights under FIFRA.

While EPA cannot, in the abstract, assess whether its use of SDTF data and any other data in connection with a specific risk assessment will give rise to compensation obligations, the analysis below provides an explanation of how the Agency would make this determination with regard to spray drift data and other data submitted to support or maintain pesticide registrations.

As provided in 40 CFR Part 152.80.-. 99, and as further explained in the preamble to those regulations at 49 FR 30,884, 30,888 (Aug. 1, 1984), an applicant is obligated to submit or cite all data necessary to satisfy EPA data requirements; applicants are not required to submit or cite all data that EPA may evaluate for the purpose of determining whether the pesticide satisfies the FIFRA unreasonable adverse effects standard or the FFDCA section 408 safety standard. Thus, EPA may utilize spray drift data, including the SDTF's data, in connection with a

registration action where no offer to pay has been made if the applicant has otherwise fully satisfied Agency spray drift data requirements. Accordingly, the critical inquiry in determining whether a given data submitter such as the SDTF is entitled to an offer of compensation is whether an applicant must rely on the submitter's data to satisfy Agency data requirements.

As you know, applicants can satisfy Agency data requirements in one of two ways: (1) By citing all data in the Agency's files (the "cite-all" method); or (2) By demonstrating compliance with each applicable requirement (the "selective method"). When the cite-all method is used, the applicant is relying upon, and offering compensation for, all relevant data in the Agency's files, so the Agency makes no determination as to whether an applicant need have offered compensation for any particular data. An offer having been made, the parties can negotiate a fair price for such data or, failing negotiations, either party may request binding arbitration under the auspices of the Federal Mediation and Conciliation Service to determine the amount and terms of compensation. When an applicant chooses the selective method, however, EPA must determine whether the data cited by the applicant satisfy the Agency's requirements. Agency data requirements are set forth in 40 CFR Part 158, but may also be established through the issuance of data call-ins (DCIs) under FIFRA section 3(c)(2)(B), or may be established on a case-by-case basis at registration, for amended registration, or reregistration (see 40 CFR section 158.75).

In assessing whether a given applicant has satisfied Agency spray drift data requirements, EPA will therefore assess the application against the existing spray drift requirements at 40 CFR section 158.440, determine whether any additional spray drift data have been required for similar products under section 3(c)(2)(B), as well as determine, as provided in section 158.75, whether any data over and above that set forth in the regulation or required by DCI are necessary to support registration. In making the latter determination, EPA will assess whether the applicant's spray drift data submissions and/or citations would be sufficient to allow the Agency to evaluate the drift characteristics of the applicant's product. If indeed the Agency would need to evaluate the results of additional spray drift data to determine the appropriateness of existing use directions and restrictions, the applicant will be required to submit or cite additional spray drift data.

It is important, however, to distinguish those circumstances where data in addition to that submitted or cited by the applicant provide useful or cumulative information, from the circumstance where the additional data are in fact necessary to evaluate adequately the registered or proposed uses of the product. In the former situation, applicants are not required to submit or cite additional data. For example, in determining the appropriate signal word (i.e., danger, warning caution) on a proposed pesticide product label, EPA takes into account not only the acute toxicology studies submitted by an applicant for registration, but also considers the same types of studies submitted by registrants of substantially similar products. Provided the applicant has submitted valid studies that satisfy EPA's acute toxicology data requirements, the applicant is not required to offer compensation to the registrants of the substantially similar

products even though EPA takes that registrant's data into account in determining the appropriate signal word. On the other hand, where the Agency's review of previously submitted data indicate that data submitted or cited by an applicant for registration are invalid or do not provide reliable results for assessing the risks (or benefits, when such information is required to be submitted) of the pesticide, the Agency will require the applicant to submit or cite that additional information.

I hope this letter clarifies the Agency position regarding the requirement for non-member applicants to cite SDTF data. If you have any questions, please call me or Jay Ellenberger at 703/305-7099.

Sincerely,

Marcia E. Mulkey, Director
Office of Pesticide Programs

cc Jay Ellenberger/FEAD
Jim Jones/RD
Elizabeth Leovey/EFED
Lois Rossi/SRRD
Margaret Stasikowski/HED
Mark Dyner/OGC
Donald R. Flint, SDTF Administrative Committee Chairman

Exhibit 5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 11, 2014

David L. Olson
United Phosphorus
630 Freedom Business Center
Site 402
King of Prussia, PA 19406

Dear Mr. Olson:

Thank you for letter of January 24th regarding the Generic Residential Exposure Task Force's (GRETF's) response to EPA's Pyrethroid Data Call-Is (DCIs).

You are correct that EPA's consideration of data in making a registration review or registration determination does not by itself compel submission or citation of data. EPA must first require those data. When EPA requires such data in connection with either registration or a DCI during registration review, applicants and registrants may choose to cite and offer to pay compensation for previously submitted data that fulfills the requirement, or they may choose to satisfy the data requirement by submitting their own studies that meet agency data requirements. Accordingly, if GRETF members choose to satisfy registration review data needs for the pyrethroids through submission of their own data, and those data meet EPA requirements, GRETF is not required to cite other data submitted, including data generated by the Residential Exposure Joint Venture (REJV), even if EPA uses the REJV data in conducting its risk assessment. However, if the data generated by GRETF do not fully satisfy the data requirements, it may have to cite the REJV to satisfy the requirement.

If you have further questions, feel free to contact Richard Dumas. He can be contacted either by phone at 703-308-8015 or by email at dumas.richard@epa.gov.

Sincerely,

Richard P Keigwin, Jr

Richard P. Keigwin, Director
Pesticide Re-evaluation Division
Office of Pesticide Program
U.S. Environmental Protection Agency
Mail Code 7508P
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Cc: Janelle Kay (Pyxis) (secretary of GRETF)
James P. Rathvon (Paley Rothman) (GRETF Counsel)
Mark Dyner (EPA/Office of General Counsel)

womblebonddickinson.com

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Voorhees, NJ

AUG 04 2021

American Arbitration Association

Exhibit 6

WOMBLE BOND DICKINSON

August 3, 2021

Womble Bond Dickinson (US) LLP

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Pressly M. Millen
Direct Dial: 919-755-2135
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Via Overnight Mail and Electronic Mail
American Arbitration Association
Case Filing Services
1101 Laurel Oak Road
Suite 100
Voorhees, New Jersey 080403
casefiling@adr.org

Re: REQUEST FOR APPOINTMENT OF ARBITRATORS UNDER FIFRA

Dear Sir/Madam:

Pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and the FIFRA Arbitration Rules at 29 C.F.R. Part 1440, Claimant Bayer CropScience LP (the "Claimant" or "BCS") hereby requests that the American Arbitration Association ("AAA") appoint a panel of three neutral commercial arbitrators from the nationwide roster of its Large, Complex Case Program to conduct a binding arbitration proceeding. No additional screening of candidates by AAA based on subject-matter experience or other criteria is requested. The Claimant requests that this proceeding be held in Raleigh, North Carolina.

The parties to the arbitration include the following:

Claimant: Bayer CropScience LP
800 North Lindbergh Boulevard
St. Louis, Missouri 63167
c/o Pressly M. Millen
Ripley Rand
Womble Bond Dickinson
555 Fayetteville Street, Suite 1100
Raleigh, North Carolina 27601
Telephone: (919) 755-2135
Facsimile: (919) 755-6067
E-mail: press.millen@wbd-us.com
ripley.rand@wbd-us.com

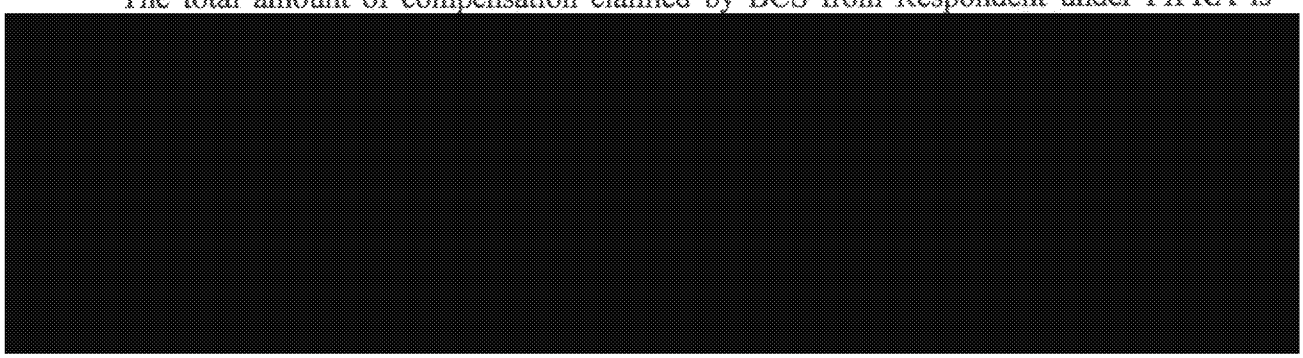
Respondent: Sharda CropChem, Ltd.
c/o James M. Wagner
Agent for Sharda Cropchem, Ltd.
7217 Lancaster Pike, Suite A
Hockessin, Delaware 19707
E-mail: jmw@wagnerreg.com
Telephone: (302) 635-7295

Claimant reserves the right to seek to add additional Sharda affiliates as parties to this arbitration where appropriate as additional facts become available.

The issue to be resolved the by AAA is the amount of compensation due to BCS from Respondent pursuant to FIFRA in consideration for Respondent's reliance on BCS data regarding the pesticide active ingredient prothioconazole. Respondent has relied on BCS's data to support Respondent's applications to the United States Environmental Protection Agency ("EPA") to register a pesticide product containing prothioconazole. An EPA registration is the federal license required by FIFRA to allow the legal distribution and sale of the pesticide in the United States.

To authorize the EPA to rely on BCS's data to support Respondent's application for registration, Respondent provided BCS with an offer to pay compensation under FIFRA, in support of Respondent's August 24, 2020 applications to register Prothioconazole Technical. BCS contacted Respondent in an attempt to reach a negotiated agreement on the amount of compensation due from Respondent for reliance on BCS's data, but Respondent refused to negotiate. The 90-day period set forth in FIFRA Section 3(c)(1)(F)(iii) has expired, and BCS is now initiating this arbitration to obtain the compensation due.

The total amount of compensation claimed by BCS from Respondent under FIFRA is



Thank you for your attention to this matter. Please do not hesitate to contact me if there are any questions about BCS's request for appointment of Arbitrators or if we can provide any further information to facilitate the AAA's administration of this case. BCS would like to expedite this procedure to the extent possible.

Sincerely,
Womble Bond Dickinson (US) LLP

Pressly M. Millen

Enclosure [redacted]

Cc: Lavonne Westbrooks, FIFRA Case Administrator, AAA
Brian Dziewa, Esq., Bayer CropScience LP
Gerret Van Duyn, Bayer CropScience LP

Exhibit 7

AMERICAN ARBITRATION ASSOCIATION
COMMERCIAL ARBITRATION TRIBUNAL

BAYER CROPSCIENCE LP	)	
and	)	Case No. 16-171-Y-00511-12
ALBAUGH, INC., AMTIDE, LLC, AND UNITED PHOSPHORUS, INC.	)	

DECISION ON MOTION OF AMTIDE, LLC AND UNITED PHOSPHORUS, INC. TO DISMISS PORTION OF CLAIMS

THE UNDERSIGNED ARBITRATORS, having been designated in accordance with the Arbitration Rules established under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"),[1] as administered by the American Arbitration Association, having been duly sworn, and having reviewed the submissions and heard the arguments of the Parties with respect to the motion dated September 12, 2013, by Respondents AmTide , LLC ("AmTide") and United Phosphorus, Inc. ("UPI") to dismiss certain studies from Claimant Bayer CropScience LP's ("Bayer's") claim against them (the "Motion"), do hereby DECIDE as follows:

I. PROCEDURAL HISTORY

1. Respondents Albaugh, Inc. ("Albaugh"), AmTide and UPI commenced this proceeding on August 29, 2012, seeking a determination of the quantum of compensation owed by each of them to Bayer, pursuant to the regulatory scheme established under FIFRA for their use of Bayer's data in connection with registration by the Environmental Protection Agency ("EPA") of their imidacloprid pesticide products.

[1] FIFRA, 7 U.S.C. §§ 136-136y. The FIFRA Arbitration Rules are codified at 29 C.F.R. Pt. 1440 (Appendix).

2. The Tribunal was constituted on March 21, 2013, and held its first preliminary hearing with the Parties, by conference call, on April 11, 2013. On May 8, 2013, the Tribunal issued a Case Management Order ("CMO") reflecting the Parties' agreements to the schedule for further proceedings, as well as a Protective Order to govern the exchange and use of confidential information in this case. Pursuant to the CMO, Bayer presented its full Statement of Claim on June 7, 2013, and the Respondents presented their corresponding Statement of Position on August 2, 2013.

3. Pursuant to the Parties' agreement in paragraph 5 of the CMO for the presentation and briefing of prehearing motions, on September 12, 2013, AmTide and UPI filed the Motion seeking to dismiss certain data studies from Bayer's claims against them.[2] Bayer filed opposition papers on October 3, 2013,[3] and AmTide and UPI filed reply papers on October 15, 2013.[4] Bayer sought and was granted permission to file a sur-reply on October 23, 2013.[5] At the request of the Parties, the Tribunal thereafter heard oral argument on the Motion on November 8, 2013.

4. The Tribunal has duly deliberated on the issues presented by the Parties, and now unanimously adopts the following ruling.

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[2] . As clarified during briefing, the final list of studies subject to the Motion is: (a) as to AmTide, Study Nos. 95, 102-103, 152-155, 175-181, 183-210, and (b) as to UPI, Study Nos. 1-15, 135-138, 346-349, 397-410. The Parties to this Motion apparently agree that most if not all of these studies will remain in the case as to the third Respondent, Albaugh. *See* Transcript of Oral Argument on Motion to Dismiss, Nov. 8, 2013 ("Tr."), 54:13-21, 84:2-13. Nonetheless, AmTide and UPI contend that resolving the Motion prior to the final hearing may contribute certain efficiencies to their preparations for this proceeding, and provide greater certainty to the moving Parties regarding the scope of their potential exposure from the claims asserted by Bayer. Tr. 54:22- 58:4-8.

[3] Claimant Bayer CropScience's Opposition to Motion to Dismiss Portion of Claims, Oct. 3, 2013 ("Opposition").

[4] Reply in Support of Motion of AmTide, LLC and United Phosphorus, Inc. to Dismiss Portion of Claims, Oct. 15, 2013 ("Reply").

[5] Claimant Bayer CropScience's Sur-Reply in Opposition to AmTide, LLC's and United Phosphorus, Inc.'s Motion to Dismiss Portion of Claims, Oct. 23, 2013 ("Sur-Reply").

II. THE RELEVANT STATUTORY REGIME

5. Under FIFRA, a company wishing to market a pesticide product must obtain a registration specific to its product, even if an identical or substantially similar pesticide already is registered by another company. Each applicant for a registration must either submit its own test data to demonstrate to EPA's satisfaction that the desired uses of the pesticide will not cause unreasonable risks to human health or the environment, or rely on other data that either is publicly available or was previously submitted to EPA by one or more other companies.

6. With respect to the use of data submitted by another company, Section 3(c)(1)(f) of FIFRA provides that an applicant for registration of a pesticide similar to one previously registered by another party need not duplicate all the data required for an original registration, but instead may rely on previously submitted data to satisfy some or all of the data requirements applicable to its application. To do so, the "follow-on" applicant must cite the relevant data in its application (using one or more of several available citation methods, discussed below) and offer to pay compensation for its use of data previously submitted, subject to certain temporal limits discussed further below, that EPA "consider[s] … in support of" the application for follow-on registration.[6]

7. The obligation under FIFRA to compensate for use of a prior registrant's proprietary data is part of what the Supreme Court has described as a "mandatory data-licensing scheme,"[7] consisting of "statutory authority for the use of previously submitted data as well as a scheme for sharing the costs of data generation."[8] Broadly stated, this scheme

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[6] FIFRA, § 3(c)(1)(F)(iii).

[7] *Ruckelshaus v. Monsanto*, 467 U.S. 986, 992 (1984).

[8] *Thomas v. Union Carbide Agric. Prods.*, 473 U.S. 568, 572 (1985).

appears to balance two competing objectives: the desire to encourage competition in the pesticide market by streamlining market entry by newer products without requiring the generation of duplicative scientific studies, while providing sufficient compensation to the initial generators of significant data so as not to disincentive them from innovation and investment.[9] This balance is achieved, *inter alia,* through a three-stage process involving the progressive relaxation, over a period of time, of the special protections accorded to original data generators.

8. In the first stage, for the first ten years following the registration of a pesticide containing a new active ingredient, a data submitter is entitled to *exclusive use* of the supporting data.[10] During this ten-year period, no subsequent applicant seeking to register a product with the same active ingredient may rely on this data, unless it has obtained written permission from the original registrant/data submitter. This exclusive use period reinforces the valuable protections available under the patent laws.

9. Second, after this initial ten-year period has elapsed, the statute authorizes the EPA to consider original data in support of applications by follow-on registrants, "within the fifteen-year period following the date the data were originally submitted," without the requirement that such follow-on registrants obtain written permission from the original

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[9] *See, e.g., Union Carbide*, 473 U.S. at 572, 573 (1985) (Congress adopted the data licensing provisions in FIFRA in recognition that "a limited proprietary interest [in the data] would provide an added incentive beyond statutory patent protection for research and development of new pesticides," while also allowing data sharing "to streamline pesticide registration procedures, increase competition, and avoid unnecessary duplication of data generation costs"); *Ruckelshaus*, 467 U.S. at 1002 ("Congress recognized that data developers … have a propriety interest in their data … [and] reasoned that submitters of data are entitled to compensation because they have legal ownership of the data") (citations and internal quotations omitted) and 1014-15 ("the public purpose behind [the] data-consideration provisions is … [to] eliminate costly duplication of research and streamline the registration process … thereby allowing greater competition among producers of end-use products").

[10] FIFRA, § 3(c)(1)(F)(i) ("With respect to pesticides containing active ingredients that are initially registered under this Act …, data submitted to support the application for the original registration of the pesticide … shall not, without the written permission of the original data submitter, be considered by the Administrator to support an

data submitted, *but only* if they have offered to compensate the original data submitter for an appropriate portion of the costs associated with such data and have provided evidence of such offer to the EPA. The time period during which EPA's authority is dependent on this precondition is defined in the following terms:

> Except as otherwise provided in clause (i) [the ten-year exclusivity period], with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration …, *the Administrator may*, without the permission of the original data submitter, *consider any such item of data in support of an application by any other person … within the fifteen-year period following the date the data were originally submitted* only if the applicant has made an offer to compensate the original data submitter ....[11]

10. Finally, after both the 10-year exclusive use period and the 15-year compensation period have elapsed for a particular set of data, the EPA may consider such data in support of a follow-on application *without* either the permission of the original data submitter or the applicant's having offered to compensate such data submitter for the use of the data.[12]

11. The only issue presently before the Tribunal in the context of the Motion is *how* the 15-year compensability period relevant to the middle stage of this three-stage process is to be calculated, *i.e.,* when it may be said that EPA "consider[s]" particular data "in support of an application" for follow-on registration, within the meaning of FIFRA section 3(c)(1)(F)(iii). AmTide and UPI contend that for any given follow-on registration, "as a matter of law" the period is measured back from the date on which EPA *granted* that registration,[13] which the Parties agree for AmTide was February 26, 2008, and for UPI

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application by another person *during a period of ten years following the date the Administrator first registers the pesticide* …") (emphasis added).

[11] FIFRA, § 3(c)(1)(F)(iii) (emphasis added).

[12] FIFRA, § 3(c)(1)(F)(iv).

[13] Motion at 1, 3.

was December 22, 2006 for their respective imidacloprid products .[14] Bayer contends that "as a matter of law" the period is measured back from the (necessarily) earlier date on which a follow-on applicant *filed its application* for such registration,[15] which the Parties agree for AmTide was August 31, 2007, and for UPI was on May 9, 2006.[16] The Parties agree that FIFRA does not expressly define when EPA "consider[s]" data "in support of" an application for follow-on registration,[17] which leaves the issue open for determination by this Tribunal.

III. THE POTENTIAL RELEVANCE OF METHODS OF DATA CITATION

12. The EPA regulations implementing the data-reliance provisions of FIFRA[18] provide that applicants wishing to rely on previously submitted data may choose one of two broad methods of data support: the "cite-all" method or the "selective" method. Under the cite-all method, the applicant indicates its intention to rely on "all data" in EPA's files that concern the active ingredient and are "pertinent to its consideration of the requested registration."[19] The applicant must issue directly to each company on the EPA's "Data Submitters List" an individual offer to pay compensation "to the extent required by FIFRA section 3(c)(1)(F) for any data on which the application relies,"[20] and also submit

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[14] Statement of Claim at 5; Motion at 5.

[15] Statement of Claim at 27; Opposition at 2; Sur-Reply at 12.

[16] Motion at 5; Opposition at 8-9.

[17] *See, e.g.,* Motion at 4.

[18] 40 C.F.R. Part 152, Subpart E (49 Fed. Reg. 30844) (Aug. 1, 1984). The regulations provide that Subpart E "describes the information that an applicant must submit *with his application* for registration ... to comply (and for the Agency to determine compliance) with the provisions of FIFRA sec. 3(c)(a1)(F)." *Id.,* § 152.80 (emphasis added). However, they also state that "[a]l information required by this subpart *should* be submitted with the application, but *may* be submitted at any later time prior to EPA's approval of the application." *Id.,* § 152.84 (emphasis added).

[19] *Id.,* § 152.86.

[20] *Id.,* § 152.86(b)(2)(ii).

to the EPA a "general offer to pay statement" as prescribed in the regulation.[21] The application must also include an acknowledgement that for purposes of FIFRA section 3(c)(1)(F), the application relies on each item of data in EPA's files which, *inter alia*, "[i]s one of the types of data that EPA would require to be submitted if the application sought the initial registration … of a product … under the data requirements in effect on the date EPA approves the applicant's present application."[22]

13. The selective method was adopted by EPA in response to litigation challenging the requirement that applicants use the cite-all method in all cases, and was designed to give applicants more flexibility in addressing data requirements, and thereby more control of their data compensation exposure.[23] Under the selective method, the applicant "may comply … by listing the *specific data requirements* that apply to his product … and demonstrating his compliance for each data requirement by submitting or citing individual studies…."[24] The second requirement — demonstrating compliance with each data requirement — allows the applicant to choose among six different sub-methods, which may be used in combination (different sub-methods for different requirements).[25] These sub-methods include, *inter alia*, submitting a new study; citing a "specific" study previously submitted to EPA together "with any necessary written authorizations or offers to pay"; citing public literature studies; or citing "all pertinent studies previously

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[21] *Id.*, § 152.86(c). The general offer is intended to protect companies that have submitted pertinent data but which EPA has not yet included on the Data Submitters List, and which therefore will not receive a direct offer to pay from the applicant. 39 Fed. Reg. 30884, 30893 (Aug. 1, 1984) (Preamble to EPA's Final Rule promulgating the data reliance regulations).

[22] *Id.*, § 152.86(d)(2)(ii).

[23] 49 Fed. Reg. at 30885, 30894.

[24] 40 C.F.R. Part 152, Subpart E, § 152.90 (emphasis added).

[25] *Id.*, § 152.90(b).

submitted" to EPA, again "with any necessary written authorizations or offers to pay."[26] The latter sub-method is known as the "cite-all option under the selective method," and essentially incorporates the features of the "cite-all" method, but only for particular specified data requirements, not for the application as a whole. In cases where the applicant has cited specific studies to satisfy an applicable data requirement, the applicant must issue an offer to pay only to the original submitter of such studies.[27] In cases where the applicant has opted to cite "all pertinent studies" to satisfy one or more applicable data requirements, the applicant must issue an offer to pay compensation to all companies on EPA's Data Submitters List, as well as submit a "general offer to pay" statement to the EPA.[28]

14. One of the complications of this case, which potentially distinguishes it from all prior arbitration decisions cited by the Parties in connection with the Motion,[29] is that there is a disputed issue of fact regarding which particular citation method(s) AmTide and UPI selected in their respective applications to EPA. AmTide and UPI each contend that they selected the cite-all method of data reliance.[30] Bayer contends that they used a combination of methods under the "selective method" umbrella, including — as relevant

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[26] *Id.*, § 152.90(b)(2), (3), (4), (5).

[27] *Id.*, §§ 152.90(b)(3), 152.93(b)(2)(iii).

[28] *Id.*, §§ 152.90(b)(5), 152.95(a), (b)(2)(iii).

[29] The Parties agree that FIFRA arbitration decisions are not binding precedent. *See, e.g.,* Statement of Claim at 6 n.3; Motion at 12; *see also* Tr. 102:6-11. The Tribunal has reviewed the decisions submitted by both Parties, and notes that in at least three of such decisions, there is no indication that the issue disputed in this Motion was even contested, much less extensively analyzed. *See Amvac Chem. Corp. and Termilind, Ltd. et al.,* Award at 20 n.10 (Aug. 15, 1999); *DowElanco and the Trifluralin Data Development Consortium and Albaugh, Inc.*, Award at 4 (June 1, 1998); *Abbott Labs. and Agtrol Chemical Products, Inc.,* Award at 6 (July 15, 1991). The Tribunal therefore gives these decisions little weight. The Tribunal notes the other decisions *infra*, only to the extent it considers their reasoning persuasive.

[30] Motion, at 5.

to this Motion — the "cite-all option under the selective method."[31] Because of this issue of fact, the Parties have addressed both methods in their submissions.

15. However, both Parties insist that the Tribunal need not make a final factual determination regarding the citation method(s) used by AmTide and UPI, for purposes of resolving this Motion. Indeed, both Parties insist that *their* preferred interpretation of the FIFRA text should prevail, even if the *other side's* position on citation method is adopted.[32] In part this stems from their respective readings of various passages in the regulations, but it also reflects a shared recognition that the most critical text for purposes of the data *compensation* requirement is the FIFRA statute itself, not the portions of the regulations which govern data *citation*.[33] The Tribunal agrees with this approach, and therefore begins its analysis in Section IV below with consideration of the statutory text, before turning in Section V to the implementing regulations, including the relevance (or not) of particular methods of data citation.

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[31] Opposition at 1-2.

[32] *See, e.g.,* Opposition at 2 ("the selective method regulations expressly provide that the 15-year compensability period is measured from 'the date of the application,'" but "even if these companies had invoked the 'cite-all' method, the 15-year period is still properly measured from the application date"); Reply at 1-2 ("Bayer's effort to create factual issues fails, because even assuming Movants' applications used the selective method, compensability of the data Movants cited is still measured from the date of registration"), 8-9 ("even if the Panel views these as factual issues, it need not decide them in order to grant this Motion. The Panel may accept for the purpose of deciding this Motion Bayer's current position that Movants submitted their applications under … the selective method with the cite-all option."), 11 ("the Panel need not reach the question of whether AmTide's and UPI's applications were submitted and reviewed under the cite-all method or the selective method using the cite-all option because it is of no legal consequence to the outcome of this Motion"), 19, 23 (similar).

[33] *See, e.g.,* Opposition at 2 ("The same passage in the statute establishes the 15-year compensability period for both the 'selective' and 'cite-all' methods. There is no reason to apply the compensability period in a dramatically different manner based on the details of the citation method a follow-on applicant chooses."), 10 ("The 15-year compensability period is based on the same statutory language, regardless of the data citation method used in each instance"); Tr. 44: 4-7 (AmTide and UPI arguing that "[i]t's the same statutory language that you are interpreting and applying and the statutory language makes no distinction between the cite-all and selective method regulations"); *see also* Tr. 48:1-6, 100:21-101:5 (AmTide and UPI) (similar); Tr. 63:15-22 (Bayer) (similar).

IV. THE STATUTORY TEXT GOVERNING MEASUREMENT OF THE COMPENSABILITY PERIOD

16. As discussed above, the language relevant to measurement of the 15-year compensability period is framed in terms of when EPA itself "*consider[s]*" an item of data "*in support of an application*."[34] The determination of which date EPA "consider[s]" any particular item is significant, because it effectively triggers a 15-year count-back: if the underlying data was originally submitted *more* than 15 years prior to the date EPA "consider[s]" that data in support of a follow-on application, there is no longer an obligation for the follow-on registrant to pay compensation, whereas if the underlying data was submitted *less* than 15 years prior to the date of EPA consideration, the obligation to pay attaches.

17. As with any case involving statutory construction, the first place to start is with the "plain meaning" of the text, to the extent it can be ascertained. FIFRA requires the EPA to "review the data after receipt of the application and …, as expeditiously as possible, either register the pesticide … or notify the applicant of [its] determination" not to register the product.[35] Necessarily, EPA's "review" of particular data does not occur in a split second. It logically involves a process, (a) commencing with *submission of an application,* (b) involving some period of time for the working of *internal EPA procedures*, and (c) culminating with EPA's *announcement of its determination (i.e.*, registration or a decision not to register).

18. In this case, neither Party suggests that the date of "consider[ation]" of data "in support of an application"[36] should depend on the actual workings of internal EPA procedures, between the submission of an application and the EPA's announcement of its

[34] FIFRA, § 3(c)(1)(F)(iii) (emphasis added).

[35] FIFRA, § 3(c)(3)(A).

determination. Although at a theoretical level such an inquiry might best approximate the plain meaning of the word "consider" — *i.e.*, when a particular responsible EPA official actually directs his or her mind to the matter at hand[37] — this would require insight into a proverbial "black box," involving internal EPA review of files. The Parties confirmed during oral argument that such information is not publicly available, and even if it theoretically could be obtained, it would create an unworkable system requiring a detailed fact-specific inquiry for each individual study that in some way is pertinent to a data requirement.[38]

19. Accordingly, the debate in this case involves a choice between two fixed dates, either the date of the application or the date of the registration, neither of which precisely measures the date that the EPA in a true sense actually "*consider[s]*" (*i.e.*, gives substantive attention to) any particular item data. Bayer contends that the "consider[ation]" date should be fixed as of the date of the application, because that is when the applicant is required to *cite* data it believes may be pertinent to applicable data requirements, and to *offer* to pay compensation for any such data that the EPA in fact "consider[s]" so pertinent.[39] AmTide and UPI, by contrast, emphasize that the final data *requirements* are

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[36] FIFRA, § 3(c)(1)(F)(iii).

[37] As noted in one prior arbitration case, Webster's New World College Dictionary (4th ed. 2004) defines "consider" in terms of directing one's mind to something, in order to understand it or make a decision about it. *See, e.g., Monsanto Company and Tacoma Ag, LLC*, Decision on Motion to Strike at 8 (Aug. 25, 2011). Other dictionaries define the word in ways that likewise suggest a *process* of assessment (not necessarily an instantaneous action). *See, e.g.*, Merriam-Webster's Collegiate Dictionary (11th ed. 2005) ("to think about carefully," synonymous with "study, contemplate, weigh"); Oxford Dictionaries Online ("to think carefully about (something), typically before making a decision").

[38] Tr. 51:13-20 (AmTide and UPI); 60:7-13, 90:16-19 (Bayer); *see also* Sur-Reply at 5 (acknowledging the hypothetical factual question, "on what date during EPA's review of a follow-on application did the EPA reviewer actually open and 'consider' the contents of each cited study," but arguing that "attempting to answer this question in each arbitration would be impossible and result in a completely unworkable process.").

[39] *See, e.g.*, Opposition at 10.

not fixed until the date the EPA announces its decision, and suggest therefore that the final moment of the EPA's "consider[ing]" data must occur at the same time.[40]

20. AmTide and UPI's approach to the text is consistent with the general understanding that words in a statute should not be construed in isolation, but rather in the context of the phrase or sentence in which they appear (together with surrounding provisions, and in light of the object and purpose of the overall statutory scheme).[41] The operative sentence refers not solely to EPA's consideration of data, but specifically to its consideration of data "in support of an application."[42] To consider data "*in support*" of an application implies not solely a process of directing one's mind to that data, but also the notion of a *conclusion* to that process, resulting in a decision that a particular item of data in fact does *support* the application rather than *contravene* it (or be wholly irrelevant to it).[43] This conclusion necessarily does not occur until EPA rules favorably on the application.

21. This interpretation of the text is also consistent with various other aspects of the statutory framework. First, as discussed above, FIFRA first accords original data submitters a 10--year period of exclusive use, measured not from the date such originators *applied* for original registration of the pesticide, but rather from "the date the Administrator first

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[40] *See, e.g.,* Tr. 35:22-36:10 (arguing that "the data requirements that must be satisfied are not the data requirements as of the date of the submission of the application. They are the data requirements under the plain terms of this regulation in effect on the approval date. It would make no sense that an applicant's compensation obligation would be … deemed from the date of application if it is the approval date from which the applicant has to satisfy all of the applicable data requirements.").

[41] *See, e.g., United Savings Ass'n v. Timbers of Inwood Forest Associates,* 484 U.S. 365, 371 (1988) ("Statutory construction … is a holistic endeavor. A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme") (citations omitted). The principle has a long history. *See* CRS Report for Congress, "Statutory Interpretation: General Principles and Recent Trends," Aug. 31, 2008, at 2-3 (noting Chief Justice Taney's statement in 1950 that "[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy").

[42] FIFRA, § 3(c)(1)(F)(iii).

[43] *See Monsanto and Tacoma*, Decision at 8 (concluding that the EPA "considers" data in support of an application when it approves an application, because "[l]ogically, that is the point in time that the EPA makes its decision based upon its data requirements in effect on that date").

registers the pesticide."[44] It would be discordant to measure their initial period of absolute protection from the date their own registrations were approved, but not to measure their secondary period of modified protection (through data compensation by follow-on registrants) from something other than the date those follow-on registrations similarly were approved.

22. The interpretation is also consistent with the underlying object and purpose of the data compensation requirement. As discussed above, FIFRA creates a three-stage process reflecting a progressive lowering of the protection provided to initial data submitters from the challenges of competition by new market entrants. The whole function of "compensation," within this framework and consistent with the ordinary usage of the term,[45] is to help to offset the harm incurred through market competition. It is consistent with this object and purpose that the compensability period be measured back from the date on which competition from a follow-on registrant becomes authorized, namely the date on which its registration is approved. There is less logic in measuring the period back from the date that a would-be competitor first seeks permission to compete, a request that by no means is guaranteed to be granted and the date of whose approval in any event is subject to considerable uncertainty. Since the original data submitter continues to enjoy freedom from competition from the follow-on applicant during the hiatus between the dates of application and approval, it would be inconsistent with the underlying rationale of "compensation" for the eventual scope and quantum of

[44] FIFRA, § 3(c)(1)(F)(i) (emphasis added).

[45] *See* Black's Law Dictionary Online (2d. ed.) (defining "compensation" as "indemnification; payment of damages; making amends; that which is necessary to restore an injured party to his former position").

compensation to be measured back from the application date, rather than the date of approval.[46]

V. REFERENCES TO DATA COMPENSATION WITHIN THE IMPLEMENTING REGULATIONS

23. As noted above, the relevant language governing the duty of data compensation appears in the FIFRA statute itself, not in the implementing regulations that govern methods of citation. This does not mean that the EPA's interpretations of the FIFRA statute are unimportant, but it does impose an obligation to ascertain, for any given passage cited in support of such a purported interpretation, whether the EPA in fact was speaking directly to the issue at hand, *i.e.,* when the EPA "consider[s] … data in support of an application," for purposes of determining the 15-year compensability period. If the EPA was speaking to corollary issues — *i.e.,* when an applicant must submit its "offer to pay," or when the final EPA data requirements are set, against which any given application must be measured — then the EPA's statement necessarily would be less persuasive on the question at hand.

24. With this in mind, the Tribunal now reviews, in chronological order, the various EPA statements invoked by the Parties in support of their respective positions.

25. First, AmTide and UPI rely on the EPA's 1977 statement in support of its then-proposed rules,[47] which envisioned that the EPA or an Administrative Law Judge award reasonable

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[46] The more protracted the period of EPA analysis between application and approval, the more this approach resonates with the underlying purpose of the statutory regime. In this case alone, the distinction between measuring the 15-year compensability period from the application date, and doing so based on the approval date, accounts for some six months worth of studies (covering 42 studies in total) for AmTide, and seven and a half months of studies (covering 38 studies in total) for UPI. *See* Motion at 5 (AmTide applied on August 31, 2007 and received approval on February 26, 2008; UPI applied on May 9, 2006 and received approval on December 22, 2006). Yet AmTide and UPI posed no competition to Bayer until the latter dates, raising significant question about the logic of measuring Bayer's compensation for eventual competition based on the former dates.

[47] 42 Fed. Reg. 31284 (June 20, 1977) (Proposed Rules).

compensation for reliance on another's data, in circumstances where the data was "considered in support of the application without the permission" of the original data submitter. The EPA explained that for purposes of this procedure,

> Data is not considered in support of an application until the Administrator (or his delegate) approves an application for registration. In order for data to be considered in support of an application, the applicant would be required to cite it .... If an item of data were withdrawn from the Administrator's consideration prior to approval of the application ... it would not be 'considered in support of the application.'[48]

26. AmTide and UPI further rely on the EPA's statement in 1979, when it promulgated the final regulations implementing the FIFRA data reliance provisions.[49] At this time, the sole proposed method of citation was "cite-all"; the regulations did not yet provide for the alternative "selective" method of citation. The EPA noted the concerns by some commentators that "applicants would be required to offer to pay for a set of data, the scope and value of which are not known to the applicant at the time registration is granted and the obligation to pay compensation becomes fixed."[50] The agency went on to suggest various ways by which applicants might reduce this uncertainty (some of which appear less practical than others), but the entire discussion was predicated on the assumption that while an *offer to pay* is made upon filing of the application, the extent of the actual *duty to pay* becomes "fixed" only "at the time registration is granted." So too was the EPA's following statement, which specifically referred to the compensability period being measured back from the date of "approval" rather than the date of filing:

> It should be noted that an applicant may have no duty to actually *pay* compensation for much of the data upon which an application is based. The statute places in the non-compensable category all data submitted to

[48] 42 Fed. Reg. at 31285; *see also id.* at 31287,.

[49] 44 Fed. Reg. 27945 (May 11, 1979) (Final Rule).

[50] 44 Fed. Reg. at 27949.

> the Agency or its predecessors prior to January 1, 1970 (and all data submitted more than 15 years before the approval of the application in question ....[51]

27. Bayer correctly notes that this discussion by EPA related to the original formulation of the regulations, which was struck down on unrelated grounds and eventually replaced with an alternate formulation permitting, *inter alia*, the use of the selective method as an alternative to the cite-all method.[52] But the new formulation did not change the operative explanations above, which were simply repeated in the 1982 commentary on the proposed new rules.[53]

28. The final version of the regulations, containing the detailed instructions for both the cite-all and the selective methods (described in Section III above), were promulgated in 1984 and are set forth in 40 C.F.R. Part 152. As noted above, the regulations referring to the cite-all method require that applications include an acknowledgement that for purposes of FIFRA section 3(c)(1)(F), the applicant relies on each item of data in EPA's files which, *inter alia*, "[i]s one of the types of data that EPA would require to be submitted if the application sought the initial registration … of a product … under the data requirements in effect on the date EPA approves the applicant's present application."[54] As Bayer notes, this language does not speak directly to when EPA "considers" any particular item of data "in support of" an application, which is the operative FIFRA text for purposes of the compensation analysis.[55] But it does confirm that the final *data requirements* against which an application is assessed are not fixed until the date of approval.

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[51] 44 Fed. Reg. at 27949 (emphasis in original).

[52] Opposition at 15.

[53] *See* Motion at 7 (citing 47 Fed. Reg. 57635 (December 27, 1982)).

[54] *Id.*, § 152.86(d)(2)(ii).

[55] Opposition at 12.

29. This is consistent with EPA's prior explanation, discussed above, that while the initial *offer to pay* must encompass a broad universe of data that the EPA ultimately *might* consider pertinent, the final *duty to pay* is fixed only upon approval, and might well apply only to a subset of data originally included in the offer, if for example in the interim the EPA has eliminated one or more data requirements. The statement moreover has *implications* for the critical question of when EPA "considers" data "in support of" an application[56]: if (as Bayer contends) the date of EPA's "consideration" of data was fixed at the date of application, the odd result would be that such consideration would encompass categories of data responsive to possible data requirements that EPA in the end concluded were *not* required for approval. There is no suggestion in either the statutory or regulatory texts that applicants should have to pay compensation for data responsive to requirements that the EPA ultimately considers unnecessary or irrelevant to its decision to approve a new registration. Nor does Bayer contend in this case that it is entitled to be paid for studies that were not required by EPA for Movants' product registrations.

30. The more logical interpretation of the statutory scheme, which is consistent with the textual analysis of the FIFRA language in Section IV above, is that the application is accompanied by a comprehensive "offer to pay" the maximum amount that might possibly be required by the EPA's review process, depending on which data requirements and therefore which specific data studies EPA ultimately considers pertinent to the

[56] A number of the prior arbitration decisions that have found the 15-year compensability period to run back from the date of approval have cited this language in § 152.86(d), in support of their interpretation of the FIFRA statutory text. *See, e.g., Monsanto Company and Tacoma Ag, LLC*, Decision on Motion to Strike at 8-9 (Aug. 25, 2011); *Monsanto Company and Tide International, USA, Inc.*, Order on Motion to Strike at 11-13 (Nov. 7, 2011). *See also DowElanco,* Award at 4 (citing § 152.86(d), although with no indication whether the issue was actually contested). The two *Monsanto* decisions also found the EPA's prior statements, cited above, to be persuasive evidence that it

application. But that offer is nonbinding — and presumably may be withdrawn at any time, along with the application itself[57] — until the EPA determines the *actual* data requirements and issues its approval, which formalizes and makes binding the new registrant's duty to pay compensation if it wishes to sell its product. Until this occurs, as discussed above, the new registrant is not legally permitted to begin competing with the original registrant.

31. Bayer relies heavily for the contrary position on language in the regulations that apply in the context of the *selective* citation method,[58] for which the applicant may combine any of six possible sub-methods to satisfy different data requirements that it must specifically identify as part of its application. One of those sub-methods involves citation of a *specific* previously submitted valid study, with a Master Record Identification Number and an associated offer to pay. In the context of such specific citation, the regulations provide as follows:

> The applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter if the study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited, and the study is not an exclusive use study.[59]

32. This provision evidently addresses the *third* stage of the progressive three-stage compensation scheme discussed in Section II above, after *both* the 10-year "exclusive use" period *and* the 15-year compensability period have elapsed. In that context, the

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considers the compensation period under the "cite-all" methodology to run back from the date on which the EPA grants a follow-on application. *See Monsanto and Tacoma*, Award at 9; *Monsanto and Tide,* Award at 11-12.

[57] As noted above, the regulations confirm that while the applicant ideally should include all required information with its initial application, additional or different information "may be submitted at any later time prior to EPA's approval of the application." 40 C.F.R. § 152.84.

[58] *See, e.g.,* Opposition at 1-2, 11, ff.

[59] 40 C.F.R. § 152.93(b)(3).

provision is merely confirming that if more than 15 years *already have elapsed* from the date of original data submission by the time a follow-on company is submitting its application, the follow-on applicant need not have authorization from, or provide an offer to pay to, the original data submitter. This is an uncontroversial proposition under *either* method of measuring the 15-year period, as data that is already more than 15 years old as of the date of application *by definition* will remain ever further outside that period as of the later date of EPA approval. No purpose would be served by requiring an applicant to solicit permission or submit an offer to pay for data which by *any* measuring approach already falls outside the compensability period.

33. Bayer suggests, however, that the provision should be read as carrying more weight than simply regulating what documents the applicant must cite or submit. According to its view, the provision reflects an authoritative EPA interpretation of the FIFRA statute, demonstrating that EPA believes it "consider[s] … data in support of an application" — for purposes of the compensation requirement — as of the date of the application itself, not as of the date the application is granted. The Tribunal acknowledges that one arbitration tribunal has read the regulation that way, in the only prior case the Parties identified which involved interpretation of the compensability period in the context of the selective method of citation.[60] That decision disposed of the issue in a single paragraph, with only limited analysis. Nonetheless, *this* Tribunal does not believe that § 152.93(b) can carry the weight Bayer suggests.

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[60] *Dow AgroSciences and Gharda U.S.A., Inc.*, Award at 2 (April 16, 2001). The Parties indicated during oral argument that they did not know whether this decision concerned solely citation of specific prior studies within the ambit of § 152.93(b), or possibly also use of the "cite all option under the selective method," which is discussed in the separate § 152.95 and which does not contain the same language. *See* Tr. 95:7-10.

34. In any event, even if Bayer were correct that the passage reveals something about EPA's thinking regarding how the compensability period should be measured, this does not mean (as Bayer argues) that the passage necessarily extends beyond its fairly limited context (citation of particular prior data studies), to inform all interpretations of the statute, regardless of the citation method selected.[61] According to Bayer, such a conclusion is mandated by the need for consistency; any other reading, Bayer argues, would result in different approaches to measurement being used for different citation methods, an intention that was nowhere stated by either Congress in enacting FIFRA or EPA in enacting its implementing regulations.[62]

35. The Tribunal appreciates the desire for an unified interpretative approach to the FIFRA statute, and acknowledges that this desire has led prior arbitration tribunals (based on their reading of § 152.93(b)(3)) to discount the EPA's prior statements discussed above.[63] But the EPA included this language (such as it is) only in one subsection of the regulations involving one sub-method of citation — a sub-method moreover that neither Party contends is applicable to the particular data studies at issue in this Motion.[64] The

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[61] Opposition at 11.

[62] Opposition at 11.

[63] *See Avecia, Inc. and Mareva Piscines et Filtration's, S.A..,* Order on Motion at 2 (Oct 29, 2001) ("While great weight must be attached to EPA's interpretation of its own statutes, this Arbitrator finds that the statements made by the EPA … are at odds with its own rule § 152.93(b)(3)(ii).... Regulatory § 152.93(b)(3)(ii) and the *Dow AgroSciences v. Gharda, USA, Inc.* finding are sensible and should apply as well to the cite-all method. The statute makes no distinction between the two methods of data citations ....); *Monsanto Company and Ritter Chemical, LLC*, Award at 25-26 & n.4 (agreeing with *Avecia* and reasoning, in light of the tribunal's reading of § 152.93(b)(iii), that "it does not seem logical to treat this issue differently simply because an applicant elected to proceed under the 'cite-all' method"; the tribunal characterized the EPA's statements as "'parenthetical' comment" which was "troubling since it is inconsistent with other more persuasive authority regarding this issue"). Other tribunals have rejected the *Avecia* reasoning, on the grounds that "[w]e are not prepared to discount EPA's interpretation." *Monsanto and Tacoma*, Decision at 9; *Monsanto and Tide*, Order at 12 (similar).

[64] Notably, while the Parties dispute whether AmTide and UPI invoked the "cite-all" method or the "cite-all option under the selective method" (see Section III above), neither contends that the studies at issue in the Motion were identified specifically in the applications, pursuant to § 152.93(b)(3). *See* Reply at 5 ("the regulation is not germane to Movant's follow-on applications .... [N]either AmTide nor UPI used the straight selective method governed by §

same language is *not* included in the next section of the regulations, which addresses the "cite all option under the selective method" that is more likely applicable to this Motion.[65] There, the regulations simply refer back to the content of the offer to pay that is provided in the basic "cite all" regulations, requiring "[a]n acknowledgment having the same wording as that specified in § 152.86(d), except that it may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected."[66] The Tribunal already has addressed the language of § 152.86(d), including the implications flowing from its reference to "data requirements in effect on the date EPA approves the applicant's present application."

36. Thus, whatever the meaning of the § 152.93(b)(3) language that Bayer invokes, the Tribunal cannot accept Bayer's suggestion that it simply ignore the EPA's placement of such language in one sub-section of the regulations that is not directly applicable to this Motion, and presume the language governs all other possible methods of citation, including the two alternatives potentially applicable to this Motion.[67] This is particularly the case given the Tribunal's reading of the statutory language itself , and in light of the contrary evidence of EPA intent in connection with its promulgation of various iterations of the regulations addressing the cite-all methodology (discussed *supra* in this Section).

37. As to the issue of consistency, the Tribunal notes that one prior set of arbitrators reasoned that:

> there is logic to treating the cite-all and selective methods differently. Under the selective method, the data are specified by the applicant in the

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152.93 to specifically cite any of Bayer's claimed studies, and Bayer does not contend otherwise."); *id.* at 9, 10 (same); *see also* Tr. 49:8-11, 52:8-20, 75:21-76:2, 97:16-20.

[65] 40 C.F.R. § 152.95.

[66] *Id.*, § 152.95(c).

[67] Tr. 79:12-19.

> application and it therefore makes sense to run the period back from the application date. In contrast, under the cite-all method, the data considered are pertinent data in EPA's files and that data cannot be determined until the application is approved.[68]

This Tribunal, by contrast, has noted that there may in fact be no inconsistency, because the text of § 152.93(b)(3) may not necessarily imply what Bayer suggests as a payment requirement, even within the subcategory of selective method citations to which it applies.

38. In any event, it is not for this Tribunal to resolve all possible inconsistencies among EPA's various statements about its complex regulatory framework, particularly those posed by an isolated passage that does not seem applicable to this Motion. This Tribunal is limited to deciding the Motion before it, which concerns a single item of *statutory* text, informed to the extent relevant by the EPA's various interpretative statements as bearing on the *citation methods possibly relevant* to the studies encompassed by the Motion. Having considered these issues carefully, in light of the Parties' arguments and all the materials submitted for review, the Tribunal concludes that for purposes of the studies before it, EPA should be deemed to have "consider[ed]" an item of data "in support of an application"[69] on the date that it grants that application and registers a follow-on product for use.

VI. CONCLUSION

39. For the reasons stated above, the Motion is hereby granted. The studies at issue on the Motion (identified in note 2 *supra*) are dismissed from this case as to the particular Respondents challenging inclusion of such studies.

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[68] *Monsanto and Tide,* Award at 13.

[69] FIFRA, § 3(c)(1)(F)(iii).

IT IS SO ORDERED:

Jean E. Kalicki	December 9, 2013
Jean E. Kalicki (Chair)	Date
S/David Lee Evans (w/ permission)	December 9, 2013
David Lee Evans	Date
S/John H. Wilkinson (w/permission)	December 9, 2013
John H. Wilkinson	Date

Exhibit 8

AMERICAN ARBITRATION ASSOCIATION
COMMERCIAL ARBITRATION TRIBUNAL

BAYER CROPSCIENCE LP	)	
and	)	Case No. 16-171-Y-00511-12
ALBAUGH, INC., AMTIDE, LLC, AND UNITED PHOSPHORUS, INC.	)	

DECISION ON MOTION OF BAYER CROPSCIENCE LP'S MOTION FOR RECONSIDERATION OF PARTIAL DISMISSAL

THE UNDERSIGNED ARBITRATORS, having been designated in accordance with the Arbitration Rules established under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as administered by the American Arbitration Association, having been duly sworn, and having reviewed the submissions of the Parties with respect to the motion dated January 24, 2014 (the "MfR") by Claimant Bayer CropScience LP's ("Bayer") for reconsideration of the Tribunal's December 9, 2013 decision (the "Decision") on the motion by Amtide, LLC and United Phosphorus, Inc. ("Amtide" and "UPI," respectively) to dismiss a portion of Bayer's claims against them, do hereby DECIDE as follows:

1. This decision presumes prior familiarity with the Tribunal's prior Decision, and does not repeat the contents thereof. Unless stated otherwise, defined terms are understood to refer to the prior definition of those terms in the Decision.

2. At the time Amtide and UPI's motion to dismiss was argued, the parties agreed that every other arbitration tribunal known to have addressed the issue under consideration — the date on which EPA "consider[s]" data "in support of" an application for follow-on

registration within the 15-year compensability window[1] — had decided that issue purely as a matter of law.[2] That was the case whether such tribunals ultimately adopted the interpretation of the FIFRA statute that Bayer offered, or the interpretation that Amtide and UPI offered. All parties at the time contended that their particular preferred interpretation of the statute could be adopted as a matter of law, based on the plain meaning of the text. *See* Decision, ¶ 11 (citing submissions). Neither party identified any precedent involving an evidentiary hearing on the interpretation of the relevant statutory text.

3. Bayer now argues, however, that it was arbitrator "misconduct"[3] for this Tribunal to interpret the language of the statute without hearing evidence. Specifically, Bayer contends that the Tribunal engaged in misconduct by construing the statutory text without first entertaining oral testimony about certain matters that it had previously described only in the most general of terms (see discussion below). In Bayer's prior submissions, it had offered such testimony only in the event the Tribunal was disinclined to accept its own preferred reading of the statutory text, stating that no evidentiary hearing would be required to accept its preferred reading, only to reject it. *See* Tr. 87:22-88:4 ("we think it's an issue as a matter of law, it could be decided in our favor…, [but] I don't believe that you can decide it in the movants' favor without looking at some of these factual assertions").

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[1] FIFRA, § 3(c)(1)(F)(iii).

[2] *See, e.g., Monsanto v. Tacoma*, Decision at 8 ("We view the interpretation of the 15-year compensability period to be a matter of law appropriate for us to decide now"); *Monsanto v. Tide*, Decision at 12 ("In the Panel's view this is a pure question of law, the decision of which will not be assisted by an evidentiary hearing"); *Avecia v. Mareva*, Order at 2-3.

[3] *See* 9 U.S.C. § 10((a)(3).

4. The Tribunal rejected this one-sided proposition that the statutory text could be interpreted as a matter of law if favorable to Bayer, but not as a matter of law if unfavorable to Bayer. In the Tribunal's view, the prior arbitrators who had grappled with the same question proceeded properly to view it as a pure issue of statutory interpretation, and this Tribunal was empowered to do the same.

5. As the Tribunal explained, its interpretation of the statutory text was consistent with the ordinary meaning of the word "consider," which implies a "process of assessment," not an "instantaneous action." Decision, n. 37. The juxtaposition in the statute of the word "consider" with the additional words "in support of" confirms that the thought process was intended to be complete when a decision was reached by EPA, in other words when it rendered a decision on registration (or non-registration) of a follow-on product. *See* Decision, ¶ 20.

6. Bayer now misconstrues that reasoning to suggest the Tribunal somehow conceded that it was interpreting the word "consider" differently than the ordinary meaning of that term. *See* MfR at 2, 8, 16 (accusing the Tribunal of defining "consider" as an instantaneous act at the moment of the final decision, rather than as a process of thought). A review of the Tribunal's actual reasoning demonstrates that it said exactly the opposite: indeed, that it was the *contrary* proposition urged by Bayer (that the EPA "consider[s]" data "in support of" an application only at the moment the application is submitted) which implied some kind of instantaneous act. Decision, ¶¶ 17-20.

7. With respect to the testimony Bayer then offered (in only the most general of terms) "to shed further light on the methods of data citation, the follow-on application process, and EPA's use of data in reaching pesticide regulatory decisions under FIFRA" (Bayer

Opposition at 20), the Tribunal concluded that such testimony was not relevant to the issue of statutory interpretation. Indeed, the parties expressly agreed that they did not advocate any reading of the statute which would turn on the specific date(s) along the continuum between the application date and the registration date that EPA personnel actually turned their minds to evaluation of a particular data file. *See* Decision, ¶ 18 & n.38 (noting, *inter alia*, Bayer's statement that "attempting to answer this question in each arbitration would be impossible and result in a completely unworkable process"). To the contrary, the parties agreed that the statute commanded the selection of a fixed "bright line" rule for compensability determinations, although they differed on whether that rule should flow from the start or the conclusion of the EPA's consideration of the follow-on application. *See* Decision, ¶¶ 18-19. Given this consensus between the parties that the EPA's interim procedures were not relevant to interpretation of the statutory text, the Tribunal concluded that proffered testimony about the practical workings of the EPA process (in Bayer's words, "how this works," from "folks … who've reviewed studies and … processed applications," Tr. 90:5-9) would be neither relevant nor material to resolution of the motion. The cases Bayer now cites, about the misconduct represented by a panel's failure to consider "relevant" evidence before adjudicating issues before it (*see* MfR at 5-6), are thus wholly inapposite. The predicate finding, that the evidence indeed would be relevant because the applicable issue could not be decided purely as a matter of law, was not proven in this case. And, as noted above, there appears to be no precedent (at least identified by the parties to the Tribunal) for treating the interpretation of FIFRA's compensation provisions as anything other a pure issue of law.

8. Bayer's new argument, that testimony respecting the inner workings of the EPA would demonstrate that the EPA is more likely to impose new additional data requirements during the time an application is pending, than to drop requirements that existed on the date an application is filed (*see* MfR at 9-10),[4] does not alter the Tribunal's reading of the statutory text. In fact this possibility reinforces the Tribunal's conclusion that the key statutory event (the EPA's "consider[ation]" of data "in support of" an application) must occur at the date it decides to grant the application, not the date when the application is first filed. If, as Bayer contends, the EPA only "considers" data as of the application date, then all data that becomes relevant later because the EPA adds new requirements for registration would end up being uncompensated, because the follow-on applicant would have the obligation only to compensate for data the EPA "considers." The Tribunal's reading of the term "consider[s] … in support of," by contrast, would require compensation for the additional data components necessary to satisfy the additional data requirements, up to the date the registration actually is granted. In short, just as it would be illogical for a follow-on applicant to be required to pay for a study that the EPA ultimately determines is utterly unnecessary for the follow-on application (by eliminating the data requirements), it would be illogical for the follow-on applicants to obtain a "free ride" with respect to studies that become relevant only as a result of the EPA's addition of further requirements. The Tribunal's reading of the statutory text is consistent not

[4] Bayer criticizes the Tribunal for not considering this possibility in its earlier Decision. MfR at 9-10. As a threshold matter, however, Bayer does not contend in its MfR that it ever *raised* with the Tribunal, in any of its written or oral submissions prior to the Decision, the possibility of EPA's expanding the applicable data requirements between the date of application and the date of registration. By contrast, both parties addressed the implications of a possible decision by the EPA to eliminate certain data requirements. Bayer's criticism of the Tribunal for addressing this issue expressly presented to it by the parties (*see* Decision, ¶ 29), and for not addressing an alternate scenario not presented to it by the parties, is therefore misplaced. A motion for reconsideration should not be based on arguments that a party failed to raise prior to the decision it now challenges.

only with the plain meaning of the term "consider," but also with the logic of these two alternative scenarios.

9. Bayer's new supplemental authority, 79 Fed. Reg. 6819 (Feb. 5, 2014), does not materially change the statutory analysis. The new Final Rule simply confirms that an applicant must submit an offer to pay when it makes its application, a point the Tribunal itself acknowledged in its earlier Decision was stated in one portion of the implementing regulations.[5] This does not address the statutory question before us, which Bayer itself acknowledged was when the *EPA* "considers" data "in support of" that application (*see* Decision, ¶ 28 & n.55) — asserted by the parties to be either the date of the application (Bayer's reading), or the date of the decision on the application (Amtide and UPI's reading). The new Final Rule is consistent with either outcome, because it simply addresses the required contents of the application, not the EPA's consideration of it.

10. Bayer's reliance nonetheless on the new Final Rule as supposed support for its position underscores the difference between its proffered reading of the statute and the one the Tribunal adopted. The fundamental flaw in Bayer's interpretation, as the Tribunal found in its Decision, is that it conflates the issues of the required contents of an application with the EPA's subsequent consideration of that application. While the former is certainly a prerequisite for the latter — and the EPA naturally may reject an incomplete application as facially deficient and thus not deserving of substantive consideration — the two analyses are fundamentally distinct. The new rule addresses the filing prerequisites, but not the process that follows. Thus, it confirms that the EPA may only proceed with

the consideration of an application if it is accompanied at the outset by a certified offer to pay; this is a wise allocation of EPA resources, so the agency need not waste time and resources on a facially deficient application, and it protects the intellectual property rights of original data generators such as Bayer. But it says nothing about which data eventually will be deemed compensatory, the scope of which can only be determined based on the data requirements considered applicable upon approval.

11. Finally, the Tribunal did not assume facts contrary to Bayer with respect to the data citation methods elected by AmTide and UPI (*see* MfR at 2, 13). Bayer contended that these Respondents elected to use the "selective" method rather than the "cite-all" method, but it did not contend that they cited in their applications *any* of the particular studies for which Bayer seeks compensation in this proceeding. To the contrary, Bayer contended that as to *all* of the studies relevant to this arbitration, the applicants used the "cite-all option under the selective method." *See* Decision, ¶ 14 & *n.* 31 (citing Bayer's submissions); ¶ 35 & n.64 (citing statements during oral argument). Bayer now confirms this earlier contention, stating that "the specific studies in Bayer's claim were cited using an option other than § 152.93" (MfR at 15-16). The Tribunal accepted that contention for purposes of the motion, thus assuming the facts to be precisely as Bayer contended them to be. *See* Decision, ¶ 35 (noting that consistent with Bayer's contention, the "cite-all option under the selective method" was the one "more likely applicable to this Motion"). The Tribunal simply decided as a matter of law, based in part on the clear regulatory text, that the "cite all option under the selective method" referred back to the

[5] Decision, ¶12 n.18. While the Tribunal observed in a footnote an apparent ambiguity in the regulations based on their concomitant statement that the required information "may be submitted at any later time prior to EPA's approval of the application," *see id.,* the Tribunal in no way rested its analysis on this provision.

general "cite all" regulations in connection with the content of a follow-on's offer to pay compensation. Decision, ¶ 35. The Tribunal also noted both parties' contentions that the precise method of data reliance used by AmTide and UPI in any event was not material, because the result would be no different under either approach urged by the parties; to the contrary, each party insisted that the Tribunal could presume the opposite citation method for purposes of the motion. *See* Decision, ¶ 15 & nn.32-33.

12. For these reasons, the Tribunal stands by its earlier ruling.[6] Notwithstanding the able briefing by both parties, the Tribunal continues to be unpersuaded that the testimony Bayer offers to present at an evidentiary hearing would have any relevance to the interpretation of the statutory terms "consider … in support of," which all prior arbitral tribunals apparently have agreed may be construed purely as a matter of law. In such circumstances, it would serve the interests neither of justice nor efficiency to delay these proceedings to hear testimony that is immaterial to a pure issue of statutory interpretation.

IT IS SO ORDERED:

Jean E. Kalicki	March 5, 2014
Jean E. Kalicki (Chair)	Date
S/David Lee Evans (w/ permission)	March 5, 2014
David Lee Evans	Date
S/John H. Wilkinson (w/permission)	March 5, 2014
John H. Wilkinson	Date

[6] The Tribunal rejects the additional arguments advanced by Bayer in its Motion for Reconsideration, as they are merely re-argument of positions considered and rejected in the Decision.

Exhibit 9

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
BAYER CROPSCIENCE LP 2 T.W. ALEXANDER DRIVE, P.O. Box 12014 RESEARCH TRIANGLE PARK, NC 27709	N/A - Prothioconazole Chemical # and Name: 113961 Prothioconazole	24-Jul-2017 GENERIC ID # GDCI-113961-1613

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Environmental Fate Data Requirements (Conventional Chemical)								
835.4100	Aerobic soil metabolism **(14)**	N				I,C,A	TGAI	24	
835.4400	Anaerobic aquatic metabolism **(17)**	N				I,C,A	TGAI	24	
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.2100	Avian acute oral toxicity test **(11, 13, 26)**	Y				I,C,A	Degr	12	
850.1010	Aquatic invertebrate acute toxicity, test, freshwater daphnids **(11)**	N				I,C,A	DEGR	12	
850.1025	Oyster acute toxicity test (shell deposition) **(10)**	N				I,C,A	DEGR	12	
850.1035	Mysid acute toxicity test **(10)**	N				I,C,A	DEGR	12	
850.1075	Fish acute toxicity test, freshwater and marine **(11, 15)**	N				I,C,A	DEGR	12	

10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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BAYER CROPSCIENCE LP 2 T.W. ALEXANDER DRIVE, P.O. Box 12014 RESEARCH TRIANGLE PARK, NC 27709	N/A - Prothioconazole Chemical # and Name: 113961 Prothioconazole	24-Jul-2017 GENERIC ID # GDCI-113961-1613

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
850.1400	Fish early-life stage toxicity test	**(11, 12)**	N				I,C,A	DEGR	12	
850.3020	Honey bee acute contact toxicity	**(5, 11, 21)**	N				I,C,A	DEGR	12	
850.3040	Field testing for pollinators	**(1, 2, 20, 22)**	Y				I,C,A	TEP	24	
850.4500	Algal Toxicity	**(11, 16)**	N				I,C,A	DEGR	12	
SS-1253	Larval honeybee chronic oral toxicity	**(8, 22)**	Y				I,C,A	TGAI	12	
SS-1254	Adult honeybee chronic oral toxicity	**(7, 22)**	Y				I,C,A	TGAI	12	
SS-1256	Acute oral toxicity--honeybee adult	**(6, 11)**	N				I,C,A	DEGR	12	
SS-1257	Acute oral toxicity--honeybee larvae	**(9)**	Y				I,C,A	TGAI	12	
SS-1316	Field trial of residues in pollen and nectar	**(3, 27)**	Y				I,C,A	TEP	24	
SS-1331	chronic whole sediment estuarine/marine invertebrate toxicity test with the amphipod leptochirus plumulosus	**(18, 23)**	Y				I,C,A	TGAI	12	

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
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1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
BAYER CROPSCIENCE LP 2 T.W. ALEXANDER DRIVE, P.O. Box 12014 RESEARCH TRIANGLE PARK, NC 27709	N/A - Prothioconazole Chemical # and Name: 113961 Prothioconazole	24-Jul-2017 GENERIC ID # GDCI-113961-1613

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
SS-1332	chronic whole sediment freshwater invertebrate toxicity test with the amphipod hyallela azteca **(19)**	Y				I,C,A	TGAI	12	
SS-1337	chronic whole sediment freshwater invertebrate toxicity test with the midge (chironomous sp.) **(19)**	Y				I,C,A	TGAI	12	
SS-1342	Semi Field Testing for Pollinators (Tunnel or Colony Feeding Studies) **(4, 22, 24, 25)**	Y				I,C,A	TEP	24	

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: N/A - Prothioconazole

DCI Number: GDCI-113961-1613

Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood

Use Categories Key:

A - Terrestrial food crop

C - Terrestrial nonfood crop

I - Greenhouse nonfood crop

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

1	USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.
2	Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.
3	Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.
4	Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
5	Tier 1 study. USEPA. 2012a. "Honey Bee Acute Contact Toxicity" Ecological Effects Test Guidelines OCSPP 850.3020. EPA 712-C-019
6	Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en
7	Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/3295
8	Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (Apis mellifera) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf
9	Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (Apis mellifera) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en
10	This test must be completed with the test material Prothioconazole-S-Methyl.
11	This test must be completed with the test material Prothioconazole-Desthio.
12	This test must be completed with Rainbow Trout (Oncorhynchus mykiss) as a test species.
13	The OCSPP 850.2100 guideline currently recommends the submission of a protocol for EPA review prior to initiation of tests conducted with passerine species. Data submitters are encouraged to consider the recommendations contained in relevant EPA reference documents (i.e., OCSPP 850.2100, EFED Guidance for reviewing OCSPP 850.2100 Avian Oral Toxicity Studies Conducted with Passerine Birds, EFED Guidance for USE when Regurgitation is observed in Avian Acute Toxicity Studies with Passerine Species) when preparing test protocols. A protocol does not need to be submitted to EPA for review prior to test initiation if it reflects these recommendations. If a data submitter elects to submit a protocol to EPA, in order to facilitate the review process, any aspects of a proposed study design that differ from this guidance should be noted and accompanied by a descriptive rationale which addresses why they are not expected to adversely impact the quality of the resulting study.
14	Testing on one soil utilizing exhaustive extractions in an attempt to minimize unextracted residues is required. For more information on unextracted residues, please visit: http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-addressing-unextracted-pesticide-residues
15	Testing on freshwater species is not required.

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: N/A - Prothioconazole

DCI Number: GDCI-113961-1613

Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood

16 Testing is required on one estuarine/marine species, Skeletonema costatum for example.

17 Testing for one sediment/water system is required with more exhaustive extractions. Exhaustive extractions need to be implemented in an attempt to minimize unextracted residues. For guidance on unextracted residues, please visit: http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-addressing-unextracted-pesticide-residues

18 Test substance must be the prothioconazole TGAI. For estuarine/marine sediment testing, tests on one amphipod species is required (e.g., Leptocheirus plumulosus).

19 Test substance must be the prothioconazole TGAI. For freshwater sediment testing, tests on an amphipod (e.g., Hyalella azteca) and a midge (e.g., Chironomus dilutes) are required. Results are required in terms of prothioconazole, prothioconazole-desthio and prothioconazole-S-methyl. A protocol must be submitted for review prior to initiating the studies.

20 See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

21 See also OECD 214: OECD.1998b. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test. http://www.oecd-ilibrary.org/environment/test-no-214-honeybees-acute-contact-toxicity-test_9789264070189-en

22 Results must be reported in terms of prothioconazole, prothioconazole-desthio and prothioconazole-S-methyl. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.

23 Results must be reported in terms of prothioconazole, prothioconazole-desthio and prothioconazole-S-methyl. A protocol must be submitted for review prior to initiating the studies.

24 Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (Apis mellifera L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en.

25 For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613-616.

26 Conduct study with one passerine species.

27 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar. Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under. Consideration of the attractiveness of the selected crop to pollinators. Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time. Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators. Consideration of the market proportion of the selected target crop(s).

Exhibit 10

Prothioconazole

Interim Registration Review Decision
Case Number 7054

September 2021

Approved by: _____

Mary Elissa Reaves, Ph.D.
Director
Pesticide Re-evaluation Division

Date: 09/29/2021

Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for prothioconazole (PC Code 113961, case 7054). In a registration review decision under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), the Agency determines whether a pesticide continues to meet FIFRA's registration standard.[1] Where appropriate, the Agency may issue an interim registration review decision before completing a registration review.[2] Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review.[3] For more information on prothioconazole, see EPA's public docket (EPA-HQ-OPP-2015-0474) at www.regulations.gov.

FIFRA[4] mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. In 2006, the Agency began implementing the registration review program. EPA will review each registered pesticide every 15 years. Through the registration review program, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and reduce risk evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects. For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.

The Agency is issuing an ID for prothioconazole so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). EPA is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services) to improve the consultation process for federally threatened and endangered (listed) species for pesticides under the Endangered Species Act (ESA).[5] The Agency has not yet fully evaluated prothioconazole's risks to federally listed species and their designated critical habitat. However, EPA will complete its listed-species assessment and any necessary consultation with the Services before completing the prothioconazole registration review. Before completing registration review, EPA will also complete endocrine screening for prothioconazole under the Federal Food, Drug, and Cosmetic Act (FFDCA).[6]

Prothioconazole is a broad-spectrum, systemic fungicide and a member of the triazolinthione fungicide group (triazole fungicides) that acts through demethylase inhibition in sterol

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] 40 C.F.R. §§ 155.56, 155.58.
[3] 40 C.F.R. § 155.56.
[4] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
[5] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[6] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

biosynthesis. Prothioconazole is classified as a Group 3 fungicide by the Fungicide Resistance Action Committee (FRAC).[7] The first product containing prothioconazole was registered in 2007. Products containing prothioconazole are registered for use as a seed treatment, in chemigation systems, and as aerial or ground sprays with both foliar and soil applications. Products containing prothioconazole are applied throughout the U.S. to control or suppress some important crop fungal diseases such as anthracnose leaf blight, *Ascochyta* blight, white mold, frogeye leaf spot rhizoctonia disease, and *Fusarium* head blight (scab). Major agricultural use sites include corn, wheat, and soybean. There is a single non-agricultural use on nursery stock for seeds and seedlings of conifers and hardwoods. There are no registrations for residential use. Because it was registered after 1984, prothioconazole was not subject to reregistration.

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use and Usage* (discussing how and where prothioconazole is used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Interim Registration Review Decision* (presenting EPA's interim decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete registration review).

A. Updates to the Proposed Interim Decision

In April 2021, EPA published the PID for prothioconazole. The Agency has made two changes to the PID in this ID. In the PID, EPA proposed additional personal protective equipment (PPE) for occupational workers treating corn seeds. However, based on feedback from the technical registrant, the Agency has determined that a reduction in the maximum application rate for corn seed treatment is adequately protective of occupational handler risks in lieu of the PPE mitigation that was proposed in the PID. Additionally, since the PID was issued, the Agency has determined that an update to the ground water advisory statement currently on labels is necessary, consistent with the Label Review Manual.[8] For more details on how public comments influenced these changes, see Section I.B. EPA has not updated the draft Human Health Risk Assessment or the draft Ecological Risk Assessment. This ID finalizes the Agency's interim decision and draft supporting documents (*Prothioconazole: Human Health Draft Risk Assessment for Registration Review* and *Prothioconazole: Draft Ecological Risk Assessment for Registration Review*), which are available in EPA's public docket (EPA-HQ-OPP-2015-0474).

B. Summary of Prothioconazole Registration Review

On January 11, 2016, the Agency formally initiated registration review for prothioconazole with the opening of the registration review docket for the case.[9] The following summary highlights

[7] Fungicide Resistance Action Committee (FRAC). 2021. FRAC Mode of Action (MoA) classification of fungicides. Available at: https://www.frac.info/fungicide-resistance-management/by-fungicide-common-name.
[8] Label Review Manual, https://www.epa.gov/pesticide-registration/label-review-manual
[9] 40 C.F.R. § 155.50

the docket opening and other significant milestones that have occurred thus far during the registration review of prothioconazole:

- January 2016 – EPA posted the *Prothioconazole Preliminary Work Plan* (PWP) (December 14, 2015), *Prothioconazole. Human Health Assessment Scoping Document in Support of Registration Review* (December 1, 2015), and *Registration Review Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Prothioconazole* (December 7, 2015) to the public docket for a 60-day public comment period.

- July 2016 – EPA posted the *Prothioconazole Final Work Plan* (FWP; June 30, 2016) to the public docket. The Agency received five comments on the PWP. The comments did not address the timeline presented in the PWP but did address the planned ecological and human health risk assessments and data requirements. The avian (passerine) acute oral toxicity (850.2100; with prothioconazole), penaeid acute toxicity (850.1045; with prothioconazole-S-methyl), and bivalve (embryo-larval) acute toxicity (850.1055; with prothioconazole-S-methyl) studies were included in the PWP. However, the planned data needs changed between the PWP and the FWP, and these studies were no longer included in the data needs in the FWP. In the FWP, EPA noted that additional aquatic invertebrate, terrestrial invertebrate (honey bee [*Apis mellifera*] Tiers I, II and III), and soil metabolism data were needed for the parent compound. Additionally, EPA noted that aquatic invertebrate, aquatic plants, estuarine and freshwater fish, terrestrial invertebrate, avian toxicity data were needed for the degradate prothioconazole-desthio, and estuarine/ marine invertebrate data were needed for the degradate prothioconazole-s-methyl.

- July 2017 – EPA issued a generic data call-in (GDCI) for prothioconazole to obtain data needed to conduct the registration review risk assessments (GDCI-113961-1613). The registrants submitted all required data except the Tier II and Tier III honey bee data (*i.e.*, semi-field/field studies). For more information, see Section III.

- September 2020 – EPA posted *Prothioconazole: Human Health Draft Risk Assessment for Registration Review* (May 15, 2020) and *Prothioconazole: Draft Ecological Risk Assessment for Registration Review* (June 30, 2020) for a 60-day public comment period. The Agency received four comments from four commenters. The Agency has summarized and responded to these comments in the PID. The comments did not change the risk assessments or registration review timeline for prothioconazole.

- April 2021 – EPA completed a Proposed Interim Decision (PID) for prothioconazole and posted the PID to the public docket for a 60-day public comment period. The Agency received three comments on the PID. For more information on how these comments impacted the risk mitigation strategy for prothioconazole, see Section I.C. and Section IV.A. Along with the PID, EPA posted the following documents to the public docket:
    - *Prothioconazole. Response to Comments on the Draft Human Health Risk Assessment for Registration Review.* (February 23, 2021)
    - *Response to Comments on the Draft Ecological Risk Assessment for Registration Review of Prothioconazole* (March 3, 2021)

- September 2021 – EPA has completed the ID for prothioconazole and will post the ID to the public docket. Along with the ID, EPA will post the following documents to the public docket:
    - *1,2,4-Triazole, Triazole Alanine, & Triazole Acetic Acid: Drinking Water Exposure Assessment for Registration Review* (September 14, 2020)

C. Summary of Public Comments on the PID and Agency Responses

During the 60-day public-comment period for the Prothioconazole PID (April 23, 2021 to June 22, 2021), the Agency received 3 public comments. Comments were submitted by the Bayer CropScience LP (the technical registrant), Beyond Pesticides, and the United States Department of Agriculture (USDA). The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. The Agency thanks all commenters for participating and has considered all comments in developing this ID.

Comments Submitted by Bayer CropScience LP (Docket ID: EPA-HQ-OPP-2015-0474-0052)

Comment: Bayer CropScience LP (henceforth referred to as "Bayer") were supportive of EPA's proposal to require medium-sized droplets to mitigate spray drift risks and indicated that medium-sized droplets provide sufficient efficacy for fungicides that require surface area coverage.

The registrant noted that seed treatment data provided to the Agency from the Agricultural Handlers Exposure Task Force (AHETF) represents the best available data for quantifying exposure while conducting seed treatment and that these data should be used to evaluate potential exposure and risk. The registrant understands that these data are still under review by the Agency. The registrant suggested that EPA reduce the maximum application rate of prothioconazole on corn seed in lieu of adding PPE, as proposed in the PID. The rate reduction proposed by the registrant would reduce the maximum allowable application rate from 3.83 fl oz active ingredient (a.i.)/ 100 lbs seed to a maximum allowable rate of 2.0 fl oz a.i./100 lbs seed, which would adequately reduce the seed treatment handler risks identified in *Prothioconazole: Human Health Draft Risk Assessment for Registration Review* (May 15, 2020). Bayer's current recommended application rates range between 0.25 fl oz a.i. /100 lb seed to 1 fl oz a.i. /100 lb seed. The maximum allowable application rate proposed by the registrant (2.0 fl oz a.i. /100 lbs seed) encompasses the recommended application rate range for commercial applications and would provide fungicidal protection and application flexibility.

In response to EPA's proposal to prohibit the use of mechanically pressurized handguns for some occupational handler scenarios, Bayer proposed that EPA prohibit the use of all handheld equipment for application of prothioconazole (backpack, manually pressurized hand wand, and mechanically pressurized handgun). Bayer suggested that use of handheld equipment in

commercial settings is not feasible to provide sufficient spray coverage and that this prohibition would not represent an undue burden for growers.

Finally, Bayer proposed adding the following statement to the Directions for Use section of the prothioconazole labels to provide a reminder to workers: "Standard clothing should be worn by agricultural field workers: shoes, socks, long pants, and long-sleeved shirts."

EPA Response: EPA thanks Bayer for their comments on the PID and considered these comments in the development of this ID.

EPA agrees that medium-sized droplets provide sufficient efficacy for fungicides and thanks Bayer for their feedback on this mitigation.

Bayer is correct that the AHETF data are still under review and have therefore not been incorporated into risk assessments or risk estimate calculations. EPA thanks Bayer for their proposal to reduce corn seed treatment application rate in lieu of the PPE mitigation that was proposed in the PID. EPA agrees that the registrant's proposed rate reduction from 3.83 fl oz a.i. /100 lbs seed to 2.0 fl oz a.i. /100 lbs seed would fully mitigate the risks to occupational handlers identified in *Prothioconazole: Human Health Draft Risk Assessment for Registration Review* (May 15, 2020). Because the registrant's proposed rate reduction would reduce the risk to occupational workers, not impact the recommended application rate range, and maintain fungicidal protection and application flexibility, the Agency considers this a valid risk mitigation option and has updated the mitigation strategy in this ID. For additional information, please see Section IV.A.

EPA thanks Bayer for their proposal to remove all handheld uses of prothioconazole. Because risks were not identified for the majority of the handheld use scenarios for prothioconazole, and risks were only associated with a limited number of scenarios with mechanically pressurized handguns, EPA has not changed the mitigation from what was proposed in the PID. For additional information, please see Section IV.A.

EPA thanks Bayer for their suggestion for additional clarifying language in the Directions for Use section of the prothioconazole labels. EPA has addressed PPE in the Directions for Use section of labels. Current labels require, at minimum, long pants, long-sleeved shirt, shoes, socks, and chemical resistant gloves. EPA believes that requirements on labels for handlers performing are adequate for mitigating risks.

Comments Submitted by Beyond Pesticides (Docket ID: EPA-HQ-OPP-2015-0474-0053)

Comment: Beyond Pesticides expressed concerns regarding the risks identified in the *Prothioconazole Proposed Interim Decision* and the risks identified in the PIDs for several other pesticides. Beyond Pesticides suggested that the risks identified are unreasonable that the mitigation measures proposed are inadequate.

Prothioconazole Specific Comments

In response to the human health risks and risk mitigation presented in the prothioconazole PID, the commenter proposed that EPA cancel the registrations of prothioconazole, citing that the proposed actions will not protect occupational handlers and non-occupational bystanders. Beyond Pesticides stated that different states adhere to state-specific pesticide laws and may not provide additional PPE to occupational handlers. Additionally, the commenter stated that prohibiting the use of mechanically pressurized handguns may decrease the likelihood of drift from the application site, but residues still remain on clothing post-application. Finally, Beyond Pesticides indicated that prohibiting occupational workers from re-entering a corn field treated with prothioconazole may have detrimental impacts on the quality and quantity of crop yield.

In response to the ecological risks to mammals and risk mitigation presented in the prothioconazole PID, Beyond Pesticides commented that spray drift reduction measures are an inadequate means to eliminate exposure to non-target species because it will not limit on-field exposure. Beyond Pesticides also noted that seed treatment language is inadequate to protect birds and mammals.

General Comments

Spray Drift, Chemical Trespass, and Exposure to Humans and Non-target Organisms

Beyond Pesticides expressed concern about the effects of pesticide drift on farmworkers and vulnerable communities, organic farms, non-target organisms (including pollinators), and the general population. Beyond Pesticides commented that label statements have proven inadequate to sufficiently mitigate pesticide drift and that there are challenges with label compliance and subsequent enforcement of drift mitigation requirements. Beyond Pesticides assumed that non-compliance is common and can be difficult to ascertain even after human and environmental damage occurs. Beyond Pesticides noted that to manage drift, information on pesticide usage (e.g., application rate, frequency, application equipment, etc.) must be known and that this requires the collection and analysis of pesticide use data which they assert EPA lacks (or has not shared with the public). Beyond Pesticides asserted that peer-reviewed and scientifically sound human and ecological toxicological endpoints used to assess risk must include low-dose and sublethal exposures and toxicity. Beyond Pesticides concluded that, in order to avoid human and non-target organism exposures, pesticide drift and chemical trespass must be eliminated.

Fungicide Resistance and Antibiotic Resistance

Beyond Pesticides stated that fungicide resistance is predictable in chemical-intensive systems, noting that FRAC Group 3 contains many pesticides that share a mode of action which may create a risk of resistance development to the group. Beyond Pesticides commented that organic farming methods promoting soil health should naturally suppress soil borne fungal pathogens, reserving fungicide use for severe foliar disease outbreaks. In addition, Beyond Pesticides expressed concern that the widespread use of triazole fungicides in agriculture may contribute to the development of antibiotic and antimicrobial resistance to medical-use triazole drugs or reduce the ability of beneficial soil microorganisms to sequester carbon among other ecological services.

Formulations and Mixtures

Beyond Pesticides stated that EPA only considers each active ingredient individually and does not consider what can occur with the synergistic effects of mixing different pesticides. The

commenter pointed to a 2020 report from the United States Geologic Survey (USGS), a National Water-Quality Assessment (NAWQA) project, which shows that 90% of water samples contain at least five or more different pesticides. The commenter pointed to a series of reports received by EPA by parties (including the Center for Biological Diversity, the inspector general, a letter from 35 congressional representatives) and research pointing to the danger of synergistic effects. Beyond Pesticides concluded that no registration can be complete without a review of the synergistic effects posed by mixtures.

Endangered Species
Beyond Pesticides provided comments focused on the EPA's duty to complete listed species effects determinations and consult with the Services, as needed, on the registration review of pesticides in accordance with the Endangered Species Act (ESA). Beyond Pesticides predicts that ESA determinations will add to any risks of concern already identified for a given pesticide and asserts that it is not acceptable to leave pesticides on the market without such determinations.

EPA Response:

Response to Prothioconazole-Specific Comments

With regards to Beyond Pesticides' concerns with the human health risks identified from use of prothioconazole, the Agency disagrees that the proposed mitigation does not adequately protect pesticide applicators and believes that the mitigation proposed for prothioconazole will decrease the risks associated with use of prothioconazole. While pesticide regulations vary from state to state, PPE requirements on pesticide labels do not vary by state. Label-required PPE are required for all applications, regardless of the geographic location or state where the application takes place. Additionally, the mitigation objective of prohibiting of the use of mechanically pressurized handguns is to limit the exposure to occupational handlers, and not to limit potential spray drift from the application site. Finally, EPA disagrees that extending the restricted entry interval (REI)for corn from 12 to 24 hours after application to protect workers would have detrimental effects on crop yield; the Agency received support for this mitigation measure from the USDA.

EPA agrees that spray drift mitigation does not limit on-field exposure and that seed treatment label language will not eliminate potential exposure to non-target birds and mammals. Under FIFRA, the Agency must balance the benefits of pesticide usage with the potential environmental impacts. The Agency determined that reducing the maximum allowable application rate for corn seed treatment is necessary to mitigate risks to occupational handlers. This mitigation will also reduce the on-field exposure to non-target animals. Based on the extent and magnitude of potential risks to non-target birds and animals and the benefits associated with the use of prothioconazole, the Agency decided not to pursue additional mitigation.

Response to General Comments
Spray Drift, Chemical Trespass, and Exposure to Humans and Non-target Organisms
Pesticide spray drift has been and continues to be of concern to EPA in its responsibility to ensure that pesticide use does not cause unreasonable adverse effects to human health and the environment. The Agency's understanding of drift and drift reduction technology and practices

have improved; however, FIFRA does not mandate a "no-drift" standard and EPA recognizes that some amount of drift may occur even when pesticides are used according to label instructions. According to FIFRA, the Agency must balance the benefits of pesticide usage with the potential environmental impacts (except in the case of dietary, residential, and aggregate human health risks), including impacts of off-field drift. Therefore, in certain circumstances, the Agency may deem some potential off-field ecological risks from drift of a particular pesticide to be acceptable in light of the benefits of its use.

When bystander risk is identified, EPA mitigates that risk on the label through mandatory drift reduction measures (e.g., maximum release height, maximum wind speed, no-spray buffer strips, prescribed minimum droplet sizes, application rate reductions) or a combination of mitigation measures to eliminate risk to bystanders from the labeled use of the pesticide.

The factors that contribute to drift are unique to each application method and depend on factors such as weather, the application site, application equipment, and applicator actions. The Agency's goal is to ensure that pesticide labeling for applicators is clear and contains adequate use directions to ensure that the use will not cause unreasonable adverse effects on human health or the environment. Additionally, the label is designed to enable enforcement authorities, including states and tribes, to take enforcement action when appropriate. EPA acknowledges that it may be difficult for enforcement authorities to determine for a particular incident whether an applicator complied with a specific product labeling. EPA notes that there may also be instances in which applicators do not follow the label. For these reasons, the Agency has prioritized ensuring that labeling directions intended to ensure that the use of a pesticide does not cause any unreasonable adverse effects due to drift clearly delineate what is "mandatory" (as described above) and what is "advisory" (statements that are intended to educate the users and promote best practices for reducing drift) as part of its drift mitigation and ensures that drift mitigation is effective, practicable, and can be easily followed by applicators. EPA welcomes recommendations from stakeholders, including state and tribal enforcement authorities, to improve the effectiveness of its labeling mitigation. Additionally, if Beyond Pesticides has specific information that would help improve labeling statement clarity and enforcement, please submit it to the EPA for consideration.

The Agency reviews pesticide usage data, when available, for use in risk and benefits assessments. These data are collected from proprietary and public sources and are summarized in the registration review documents. These describe the use parameters on which the associated risk estimates and the pest management benefits associated with the pesticide use and impacts of the mitigation are based. When the Agency lacks use and usage information for a particular chemical or use pattern, it may solicit such information during the registration review public comment periods.

EPA's spray drift analyses in its risk assessments are based on upper-bound assumptions about application equipment and their usage and assumes that the maximum labeled use rate is applied. Because of these conservative assumptions, EPA is confident that the mitigation placed on labels to address off-field risk will be effective so long as applicators follow the labeling directions. EPA has concluded that the labeling statements included in this ID will ensure that the FIFRA standard is met and, specifically, that pesticides are used in a manner that does not result in

"unreasonable adverse effects on the environment." Please see Section IV.A.4 and Appendices A and B of this document for EPA's drift mitigation strategy for prothioconazole.

Fungicide Resistance and Antibiotic Resistance

Generally, known field resistance to a particular active ingredient in a given Fungicide Resistance Action Committee (FRAC) Group strongly suggests that resistance to other members of the group may also be occurring. For fungicides, there is reason to believe that cross resistance may not be obvious among group members and that the extent of resistance may vary between active ingredients within a group, amongst fungal species, or within a given species. For Group 3 fungicides, the FRAC estimates the intrinsic risk for resistance evolution to be medium.[10] The risk of fungicide-resistant pathogen populations may be reduced by methods such as tank-mixing and rotating alternate products that have different mode of actions to avoid back-to-back treatments with any one site-specific fungicide. Various non-chemical disease control measures may be used in concert with chemical agents, such as the group 3 fungicides, to manage fungal pathogens as part of an Integrated Pest Management (IPM) program. IPM is a key strategy to avoid or delay the evolution of fungicide resistance as effective use of nonchemical strategies can help manage disease. However, nonchemical methods of disease control are often ineffective as a standalone control measure and may not be applicable for all crops. Therefore, the use of chemical fungicides is necessary to effectively manage many diseases.

The extent to which the use of antimicrobial pesticides in plant agriculture contributes to the emergence of antimicrobial resistant pathogens, particularly those that cause infections in humans, is unknown. However, EPA is aware of increased global incidence of triazole-resistant *Aspergillus fumigatus* infections and the identification of resistance mechanisms linked to agricultural triazole use. EPA is working with federal partners to assess the potential impact of increased fungicide use in the United States on the development of triazole-resistance in medical settings. The Agency considers it critical that a variety of mode of action (MOA) groups remain available for use in the interest of suppressing resistance development to both agricultural and public health pathogens. For more information, see Section IV of this document and PRN 2017-1 and PRN 2017-2, available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.

Formulations and Mixtures

The EPA is currently developing an agency policy on how to consider claims of synergy being made by registrants in their patents. On September 9, 2019, the EPA published in the Federal Register for public comment an Interim Process for Evaluating Potential Synergistic Effects of Pesticides During the Registration Process (84 FR 47287), available at regulations.gov in docket EPA-HQ-OPP-2017-0433. After the agency has received and considered public comment on the proposed policy, and once that policy has been finalized, the EPA will consider its implications on the EPA's final decision for [CHEMICAL]. EPA assesses the risk potential of a formulated pesticide product by evaluating the relative toxicity of the active ingredients, and the formulated product. The January 23, 2014, *Overview of the Ecological Risk Assessment Process in the*

[10] FRAC Code List 2021. Available at https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2021--final.pdf?sfvrsn=f7ec499a_2

Office of Pesticide Programs[11] provides guidance on the evaluation of formulated pesticide products containing more than one active ingredient and allows for consideration of toxicological testing that may identify formulations with toxicity in excess of individual active ingredients. Formulated product toxicity data are evaluated and included in the risk assessment when available. In situations where available toxicity data indicate that a pesticide formulation may be more toxic to non-target organisms than indicated by single active ingredient testing, the Agency may request additional data on formulated products.

Endangered Species
EPA acknowledges the importance of completing listed-species effects determinations and any necessary ESA § 7 consultation with the Services (U.S. Fish and Wildlife Service and the National Marine Fisheries Service) for registration review. In circumstances where EPA has not yet made effects determinations, the Agency has considered whether the proposed label changes are expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range or critical habitat co-occur with the use of the pesticide. Before issuing a *final* registration review decision, EPA will complete effects determinations and consult, as necessary, with the Services. See the Listed-Species Assessment section in Appendix C of *Prothioconazole Proposed Interim Decision for Registration Review* for more information on EPA's ongoing collaborative work with the Services and USDA to improve the consultation process for listed species for pesticides.

Comments Submitted by USDA (Docket ID: EPA-HQ-OPP-2015-0474-0051)

Comment: USDA is supportive of most of the mitigation proposed by EPA in the PID. However, USDA is concerned with EPA's proposal to prohibit all mechanically pressurized handgun uses for forest nurseries and requested that EPA maintain application flexibility because prothioconazole is a critical tool for the forest nursery industry. USDA recognizes that stakeholder input indicated that mechanically pressurized handguns are rarely used in forest nurseries. However, USDA suggested that EPA consider a PF-10 respirator for occupational handlers in forest nurseries, rather than prohibiting mechanically pressurized handguns. USDA noted the risk estimate for use of mechanically pressurized handguns in nurseries is not of concern when a PF-10 respirator is used.

EPA Response: EPA thanks USDA for their comments and considered these comments when developing the mitigation strategy for this ID. The development of the mitigation strategy included the consideration of the potential burden on workers (e.g., potential heat stress) from a requirement to add respirators to maintain the use of mechanically pressurized handguns. EPA agrees that prothioconazole is a critical tool for the forest nursery industry and so on the advice of the USDA and agrees that the risk estimate for use of mechanically pressurized handguns in nurseries is not of concern when a PF-10 respirator is used. However, based on information provided by the Auburn University Southern Forest Nursery Management Cooperative, nurseries do not use handheld equipment when applying prothioconazole and this mitigation strategy

[11] http://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf

would not have impacts on this industry.[12] Therefore, EPA has not changed the strategy for mitigating risks to occupational workers using mechanically pressurized handguns.

II. USE AND USAGE

Prothioconazole is a broad-spectrum systemic fungicide registered for use on various agricultural sites, including seed treatments. Use sites include various fruit (*e.g.*, berries), vegetable (*e.g.*, peas and beans), and field crops (*e.g.*, corn, cotton, soybeans), and nursery-grown conifer seedlings. Applications can target crop foliage, seeds, or soil. Prothioconazole products are formulated as flowable concentrates and can be applied pre-plant, and both before and after crop emergence. Applications can be made using ground, aerial, seed treatment equipment, and chemigation.

On average from 2015-2019, about 9.2 million total crop acres were treated annually with approximately 700,000 pounds of prothioconazole.[13] In terms of total acres treated per year, 90% of prothioconazole was applied to spring wheat, winter wheat, soybean, and field corn; about 2 million acres of each crop were treated annually with prothioconazole.[11] Average single application rates of prothioconazole ranged from less than 0.1 lb a.i. per acre in spring wheat and peanuts to nearly 0.2 lb a.i. per acre in sugarbeet.[11] The average single application rate for blueberries was 0.18 lb a.i. per acre.[11]

In terms of percent crop treated, between 2015-2019, approximately 40% of sugar beet acres were treated with prothioconazole annually, followed by spring wheat (20%), peanuts (15%), winter wheat (10%), and dry beans and peas (10%).[14] In addition, the United Stated Department of Agriculture National Agricultural Statistics Service (USDA NASS) reports that approximately 10% of blueberry acres were treated with prothioconazole annually during the same period.[15]

Most crops were treated with prothioconazole once annually.[11] On average from 2015-2019, two applications of prothioconazole were made to about 10% of sugar beets, field corn, winter wheat, and dry beans and peas annually.[11] Peanuts were treated an average of two times annually.[11]

Usage data are not available for all registered uses. An unknown amount of prothioconazole is used in conifer nurseries as these sites are not surveyed for agricultural pesticide usage. Additionally, usage estimates are not available for seed treatments at this time.

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[12] Wernsman, D., 2021. Federal Registrations Manager at Bayer Crop Science LP. Personal communication received via email to EPA on July 19, 2021. The Auburn University Southern Forest Nursery Management Cooperative (SFNMC) assisted Bayer with obtaining the pine nursery registration for prothioconazole. Bayer consulted with SFNMC regarding potential impacts of prohibiting hand held uses of prothioconazole in forest nurseries. SFNMC indicated that at no time do nurseries use a hand wand application for prothioconazole and that this mitigation strategy would have no impacts on the use in forest nurseries.

[13] Kynetec USA, Inc. 2020. "The AgroTrak® Study from Kynetec USA, Inc." iMap Software. Database Subset: 2015-2019. [Accessed January 2021].

[14] Kynetec USA, Inc. 2020. "The AgroTrak® Study from Kynetec USA, Inc." Microsoft Access Database. Database Subset: 2015-2019. [Accessed January 2021].

[15] United States Department of Agricultural National Agricultural Statistics Service (USDA NASS). 2020. QuickStats. Database Subset: 2015-2019. Available at: https://quickstats nass.usda.gov/ [Accessed January 2021].

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized the 2020 human health risk assessment (HHRA) below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of prothioconazole. For additional details on the 2020 HHRA, see *Prothioconazole: Human Health Draft Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2015-0474).

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

Partially refined acute and chronic dietary (food plus drinking water) exposure assessments were conducted for prothioconazole. The acute and chronic assessments for food and drinking water indicate that dietary risks do not exceed the Agency's level of concern (LOC), which is <100% of the acute population-adjusted dose (aPAD) and <100% chronic population-adjusted dose (cPAD) for all population subgroups.

No acute dietary endpoint was identified for the general U.S. population, but an endpoint was established for females aged 13-49. Therefore, females aged 13-49 was the only population subgroup included in the acute dietary assessment. The acute exposure was estimated to be 41% of the aPAD. EPA concluded that acute dietary risks are not of concern for prothioconazole exposure.

The chronic dietary exposure was estimated to be 34% of the cPAD for the general U.S. population. The highest exposure was estimated to be 80% of the cPAD for infants (<1 year old). Chronic dietary risk estimates are below the LOC for the U.S. population and all population subgroups and are not of concern.

The Agency concluded that the prothioconazole is "not likely to be carcinogenic to humans." Therefore, a cancer dietary exposure assessment was not conducted and cancer risks from dietary exposure are not anticipated.

Residential Handler Risks and Residential Post-Application Risks

There are no products containing prothioconazole that are registered for residential uses. Therefore, a residential assessment was not completed, and residential risks are not likely.

Bystander Risks

Bystander risks of concern were not identified for prothioconazole. A quantitative spray drift assessment was conducted. Dermal risk estimates were calculated for adults and children 1 to < 2 years old. Incidental oral risk estimates were calculated for children 1 to < 2 years old. Adult dermal and children's dermal and incidental oral exposures for adults and children

from aerial and ground boom applications are not of concern at the field edge, with margins of exposure (MOEs) ranging from 580 to 1,500,000 where the LOC is 100.

Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources: food (dietary), drinking water, and residential exposures. The Agency sums the exposures from these sources and compares the aggregate risk to quantitative estimates of hazard. EPA considers the route and duration of exposure when assessing aggregate risks. For prothioconazole, aggregate exposures are equivalent to dietary exposure estimates and were not of concern.

Cumulative Risks

The Agency has not made a common-mechanism-of-toxicity-to-humans finding for prothioconazole and any other substance. Although the triazole fungicides all share the metabolite 1,2,4-triazole and its acid-conjugated metabolites (triazole alanine (TA) and triazolyl acetic acid (TAA), these substances do not contribute to the toxicity of the parent triazoles. The Agency has determined that the toxicological effects resulting from exposure to these metabolites are different from that resulting from exposure to prothioconazole. Prothioconazole does not appear to produce any other toxic metabolites produced by other substances. Therefore, EPA has premised this ID and the underlying risk assessments on the belief that prothioconazole does not have a common mechanism of toxicity with other substances.

Occupational Handler Risks

There is a potential for occupational exposure to prothioconazole associated with occupational handler activities (*i.e.*, mixing, loading, applying and commercial seed treatment) for the registered uses of products containing prothioconazole. Potential routes of exposure include both dermal and inhalation. The dermal toxicity endpoint was established based on increased incidence of supernumerary rib (14^{th} rib) in a dermal developmental rat study. Since a subchronic inhalation study was not recommended for prothioconazole,[16] inhalation toxicity was assessed using an oral developmental toxicity study in rabbits. The toxicity endpoint was based on structural alterations including malformed vertebral body and ribs, arthrogryposis (reduced muscular development/growth in newborns), and multiple malformations. For this endpoint, inhalation exposure was assumed to be equivalent to toxicity by the oral route of exposure. Because similar effects (structural alterations) were the basis for the endpoints selected for dermal and inhalation exposure, these exposures were combined to estimate risk.

Most occupational handler dermal, inhalation and combined risk estimates did not result in risk estimates of concern (MOE $\geq$ LOC of 100) with baseline attire (*i.e.,* long-sleeve shirt, long pants, socks and shoes). However, combined risk estimates were of concern (MOE < LOC of 100) for occupational handlers performing multiple activities during seed treatment of corn seeds. The total MOE was 76 for occupational workers wearing the label-required single layer of clothing

[16] J. Van Alstine, Prothioconazole: Summary of Hazard and Science Policy Council (HASPOC) Meeting of January 17, 2013: Recommendations on the Need for a Subchronic Inhalation Toxicity Study. 02/21/2013, TXR 0056563

and gloves while conducting seed treatments at the maximum labeled application rate (3.83 fl oz/100 lbs seed). With the addition of coveralls, the total MOE would be 100 and risks would not be of concern.

Additionally, the combined dermal and inhalation risk estimates were of concern for occupational handlers mixing, loading and applying liquids with mechanically pressurized handguns to orchards and vineyards,[17] typical field crops,[18] and nursery ornamentals (pine and conifer seedlings).[19] For the nursery ornamental scenario, the addition of an assigned protection factor 10 (PF10) respirator would make this scenario no longer of concern. The total MOE is 35 for occupational workers preforming this task on nursery ornamentals wearing the label-required single layer of clothing and gloves. With the addition of an PF10 respirator for this scenario, the total MOE would be 100 and does not represent a risk of concern. The total (combined) risk for the typical field crop and orchard/vineyard scenarios is driven by dermal exposure, therefore, additional respiratory protection would not improve the total MOE. For orchards, vineyards and typical field crop scenarios, the combined dermal and inhalation risks were still of concern with additional PPE (coveralls) beyond what is already required by the labels (single layer and gloves). For the field crop and orchard/vineyard scenarios, the risks to occupational workers total MOE would be 54 for occupational workers performing these tasks while wearing the label-required single layer of clothing and gloves. With the addition of a second layer (coveralls), the total MOEs for both scenarios would be 78 and would still be of concern (MOE < LOC of 100).

Occupational Post-Application Risks

Based on the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for re-entry workers exposed to indirect residues of prothioconazole resulting from outdoor uses. As described above, the dermal toxicity endpoint was established based on increased incidence of supernumerary rib (14th rib) in a developmental rat study. For most crops, scenarios for post-application activities resulted in dermal MOEs greater than the LOC of 100 on Day 0 (12 hours after application), and therefore are not of concern. However, sweet corn detasseling and hand-harvesting activities resulted in an MOE of 85 at Day 0 following application, indicating a risk of concern. On Day 1 (24 hours after application) following application, the MOE is 270 and is no longer of concern. The current restricted-entry interval (REI) for products containing prothioconazole is 12 hours.

2. Human Incidents and Epidemiology

EPA reviewed prothioconazole incidents reported to both the Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk (SENSOR). As of EPA's latest search on February 24, 2020, IDS showed 19 low- to medium-severity incidents reported from January 1, 2015 to January 31, 2020. Of these 19 incidents, there were 15 incidents reported to the Aggregate IDS involving prothioconazole, all of which were classified as minor severity. There were four incidents reported to the Main IDS involving multiple active ingredients that were classified as moderate severity. As of EPA's latest search on February 24, 2020, SENSOR

[17] Bushberry subgroup 13-07B, Low growing berry subgroup, except strawberry subgroup 13-07H
[18] Cucurbit Vegetables (Crop Group 9), Corn, sweet, Garbanzos (including chickpeas); Lentils
[19] Shortleaf loblolly, Slash, Longleaf and other pines, other conifers, other hardwoods

showed three low-severity cases reported from 2012 to 2015. All three cases were reported following a single exposure event in North Carolina in 2014. The Agency intends to monitor human incidents for prothioconazole and will conduct additional analyses if necessary.

3. Tolerances

Prothioconazole is registered for uses that result in residues in or on food. Generally, a tolerance or tolerance exemption must cover the residues; otherwise, the affected food is considered adulterated.[20] All of the necessary tolerances are in place to cover residues resulting from prothioconazole's legal use.

The Agency has established tolerances for prothioconazole under 40 CFR § 180.626. During the risk assessment process, EPA determined that additional tolerances are not necessary to cover residues in or on food from uses of prothioconazole, but EPA does anticipate revisions to several current tolerances, as explained in Section IV.C.

4. Human Health Data Needs

The human health database for prothioconazole is considered complete. The Agency does not anticipate any further data needs for prothioconazole.

B. Ecological Risks

The Agency has summarized the 2020 ecological risk assessment (ERA) below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of prothioconazole.[21] For additional details on the 2020 ERA, see *Prothioconazole: Draft Ecological Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2015-0474).

1. Risk Summary and Characterization

Because prothioconazole degrades quickly in the soil to other residues which have equal or greater toxicity to some organisms relative to that of the parent, prothioconazole and its major degradates (prothioconazole-desthio and prothioconazole S-methyl) are considered the Residues of Concern (ROC). A total residue (TR) approach was used to assess aquatic exposure and determine Estimated Environmental Concentrations (EECs) of prothioconazole and its two major degradates. The EECs were compared to toxicity endpoints of parent prothioconazole or the most toxic degradate when available.

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[20] 21 U.S.C. §§ 342, 346(a).

[21] The 2020 ERA only addresses potential risks to species not listed under the Endangered Species Act. EPA is working with its federal partners and other stakeholders to implement a Revised Method (EPA-HQ-OPP-2019-0185-0054) for assessing potential risk to federally listed species and their designated critical habitats. The Agency will complete prothioconazole's listed-species assessment once EPA has fully implemented the scientific methods necessary to complete listed species' risk assessments. For more details, see Appendix C.

Terrestrial Risks

Mammals

For foliar applications, acute dose-based risk quotients (RQs) were below the LOC (acute risk LOC=0.5) for all scenarios, where RQs that exceed the LOC are of concern. Based on the available information, the Agency concluded that there are no acute dose-based risks of concern to mammals from foliar applications.

Chronic RQs for mammals exposed to prothioconazole ROC exceeded the chronic risk LOC of 1 for foliar and seed treatments to multiple food items. The most sensitive chronic toxicity endpoint was observed in the two-generation reproduction study in rats. Reduced body weight (8-15%) and pup survival (21-33%) were observed in both offspring generations. Using upper-bound Kenaga exposure values and a default foliar dissipation value of 35 days to model risks from chronic exposure, dose-based RQs ranged from 0.02-5.8 and (for some scenarios) exceed the chronic risk LOC. The highest of these RQs corresponded to exposure to small mammals foraging on short grass. Dose-based RQs exceeded the chronic risk LOC for all uses and size classes of mammals foraging on short grass, tall grass, broadleaf plants and arthropods. Further characterization of the chronic dose-based risks to mammals was assessed using the mean Kenaga exposure values, rather than the upper-bound exposure values. However, based on mean Kenaga exposure values, RQs still exceed the chronic risk LOC for small and medium-sized mammals foraging on short grass and arthropods and for small-sized mammals foraging on broadleaf plants. When the upper-bound Kenaga EECs were compared with the lowest observed adverse effect concentration (LOAEC) instead of the no-observed adverse effect concentration (NOAEC), there were still chronic LOC exceedances for small and medium-sized mammals foraging on short grasses. Taken together, these estimates suggest that risk of concern to mammals may occur from chronic exposure to prothioconazole.

Risks outside the treated field resulting from exposure to drift residues are quantified as the distance from the field edge at which the RQ will no longer exceed the LOC (the "effects distance"). For ground application based on Tier I terrestrial point deposition estimates, the effects distance was estimated as 16 feet when applications were made with very fine to fine droplets spray droplets. If medium/ coarse droplet sizes were assumed, effects distance was estimated as 3 feet. The effects distance was also estimated for aerial applications. Under these assumptions, the effects distance is 154 feet with very fine to fine droplets and 26 feet with medium/coarse droplets.

For seed treatment scenarios, no acute risks of concern are expected for mammals consuming treated seeds as RQs ranged from 0.00 to 0.03 and are below the acute risk LOC of 0.5. Chronic risks were identified for all size classes of mammals consuming treated corn and cotton seed and for small- and medium-sized mammals consuming treated alfalfa seed (RQs ranged from 1.0 to 10). Additionally, the home ranges for all mammalian size classes are larger than the foraged area of concern, indicating that there is potential for risk to all size classes of mammals consuming treated corn, cotton and alfalfa seed. However, small-sized mammals would need to consume a large portion of their diets solely as treated corn seed (69%) to exceed the chronic risk LOC. Medium-sized mammals would need to exclusively consume treated corn seed (100% of

diet) to exceed the chronic risk LOC. Furthermore, large mammals consuming treated corn seed and all sizes of mammals consuming treated cotton and alfalfa seed would have to consume 2-20 times more than their daily diet to exceed the chronic risk LOC. This suggests that chronic risks of concern to mammals from prothioconazole-treated seeds are likely only for small and medium-sized mammals consuming corn seeds as the majority of their diet.

Birds, Reptiles, and Terrestrial-Phase Amphibians

There were no exceedances of either acute (LOC=0.5) or chronic risk LOCs (LOC=1) for birds as a result of foliar or soil directed applications. Since birds serve as surrogates for reptiles and terrestrial-phase amphibians, risk estimates for birds extend to these other taxa as well. Therefore, the Agency concludes that the likelihood of adverse effects to birds, reptiles or terrestrial-phase amphibian from acute or chronic exposure resulting from foliar and soil-directed applications of products containing prothioconazole is low.

For seed treatment applications, no acute risks of concern were expected for birds consuming treated seeds. However, the chronic RQs for all size classes of birds consuming treated corn seeds exceeded the LOC (RQs were up to 2.1, LOC=1.0). All other seed treatment scenarios for corn and all seed treatment scenarios for other seed types are not of concern. The avian chronic toxicity endpoint was established based on a reproductive toxicity test with the Mallard Duck (*Anas platyrhynchos*). However, no adverse effects were detected in this study (*i.e.*, the NOAEC is based on highest dietary concentration tested). Given the absence of detectible adverse effects in the mallard reproductive toxicity test, the chronic risk estimates for birds consuming treated corn seeds represent an uncertainty, and not a definitive risk finding.

Based on the estimated maximum seed size that small and medium birds will consume (60 mg and 120 mg, respectively)[22] and the average weight of one corn seed ($\leq$ 270 mg), it is likely that corn seeds are too large to be consumed by small to medium sized birds. Approximately 117 common species of birds are associated with agricultural fields or their adjacent edge habitats and 89 (76%) of those species are passerines, which are small sized birds.[23] Taken together, this suggests that only a small portion of birds associated with agricultural fields or their adjacent edge habitats are actually able to consume corn seeds. There is some uncertainty with using size of seed as a limiting factor for consumption and extrapolating to all small and medium-sized species, especially because the toxicological endpoint was established using a waterfowl species (Mallard Duck). However, EPA considers this approach reasonable for foraging birds. There is additional uncertainty with the degree to which larger bird species would consume the large-sized seed corn.

For all size classes of birds, the home ranges are larger than the foraged area of concern, suggesting that a bird's diet would not exclusively come from treated food items. Birds of any

[22] Benkman, C.W. and H.R. Pulliam. 1988. Comparative Feeding Ecology of North American Sparrows and Finches. Ecology. 69: 1195—1199.
[23] USEPA. 2016. Refinements for Risk Assessment of Pesticide Treated Seeds - Interim Guidance. March 31, 2016. Environmental Fate and Effects Division. Office of Pesticide Programs. U.S. Environmental Protection Agency. Available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/refinements-risk-assessment-pesticide-treated-seeds.

size class would need to consume 1.6 to 6.4 times their daily diet to be exposed to high enough levels of prothioconazole to exceed the chronic risk LOC. Considering the risks, characterization, and uncertainties, while there is a possibility of exposure, the likelihood of adverse effects on birds from prothioconazole-treated seeds is low.

Terrestrial Invertebrates

Risk quotients for adult and larval honey bees on an acute contact or oral exposure basis were not calculated because available toxicity data indicated no significant mortality or notable sub-lethal effects up to the highest doses tested for both honey bees and bumble bees (*Bombus spp.*). Honey bees serve as a surrogate for both *Apis* and non-*Apis* bees; therefore, EPA does not believe that acute risks to bees from exposure to prothioconazole are likely given that RQ values are below the acute risk LOC of 0.4.

Chronic risks of concern to larval honey bees were identified for prothioconazole use on corn and low-growing berries (RQs range from 1.1 to 1.2, LOC=1.0). However, no risks of concern were identified for adult worker honey bees foraging for nectar (RQs range from 0.19 to 0.22). Chronic larval risks were based on a NOAEL above which there was a 19% reduction in adult bee emergence in a chronic larval toxicity study with prothioconazole. If the RQ had been based on the LOAEL, chronic RQ values would drop below the chronic risk LOC. Two semi-field colony-level studies were conducted to evaluate effects from exposure to prothioconazole following foliar applications at rates of 0.178 and 0.187 lb a.i./A. In a colony-feeding study, bees were exposed to a prothioconazole-treated liquid diet where concentrations were 16 times greater than the EEC of nectar for foraging bees. Based on preliminary reviews of these three colony-level studies, no colony-level effects from exposure to prothioconazole were detected.

The distance from the treated field edge where RQs exceed the chronic level of concern for larval bees from ground and aerial applications of prothioconazole were assessed to determine potential risk to bees from spray drift exposure to prothioconazole off the site of application. For ground applications to corn, when modeling with both American Society of Agricultural Engineers (ASAE) fine droplet size and medium/coarse droplets RQ are estimated not to be of concern beyond 3 feet from the field edge for both droplet sizes. For aerial applications to corn, when modeling with both ASAE fine droplet size and medium/coarse droplets RQ are not expected to extend beyond the edge of the treated field edge.

In a chronic larval toxicity test, chronic exposure to the technical grade active ingredient (TGAI) of prothioconazole resulted in a 19% reduction in adult emergence at the LOAEL. In a chronic adult toxicity study with technical end use product (TEP) there was 53% mortality of adult bees exposed at a treatment level of 46.5 µg a.i./bee/day. Additionally, there was one incident reported associated with the use of prothioconazole in which four colonies were reported as lost; however, investigation of the incident determined that no link could be found between the loss of the bees and pesticides applied in the vicinity of the apiaries. For more information, see Section III.B.2. Despite the adverse effects observed in the chronic adult toxicity study and the one incident reporting colony loss, preliminary review of colony-level studies does not suggest that adverse effects result to bee colonies when bees were either exposed while actively foraging or treated directly in the diet.

EPA relies on data about honey bees as a surrogate for *Apis* and non-*Apis* bees. Based on the available data, EPA concludes that prothioconazole uses do not present risks of concern to bees based on preliminary review of colony-level studies.

Terrestrial Plants

No risks of concern as a result of labeled uses of products containing prothioconazole were identified for terrestrial plants. While the Agency does not believe that risks to terrestrial plants are likely to result from use of products containing prothioconazole there are 16 plant-related incidents in the Incident Data System associated with the use of prothioconazole. Therefore, there is some uncertainty regarding potential adverse effects to terrestrial plants and the Agency will continue to monitor incident reports and available data to determine whether adverse effects are occurring.

Aquatic Risks

Freshwater Fish and Aquatic-Phase Amphibians

There were no acute or chronic risk LOC exceedances (acute risk LOC =0.5; chronic risk LOC=1.0) for freshwater fish. Since freshwater fish serve as surrogates for aquatic-phase amphibians, risk estimates for freshwater fish extend to this life stage of amphibians as well. Therefore, the Agency does not believe that adverse effects to these freshwater species are likely to result from exposure to prothioconazole as a result of currently registered uses.

Estuarine/Marine Fish

While there were no chronic toxicity data available for estuarine/marine fish and toxicity estimates were generated using an acute-to-chronic ratio value of 77 based on freshwater fish, there were no acute or chronic risk LOC exceedances for estuarine/marine fish. Therefore, the Agency does not believe that risks to estuarine/marine fish are likely to result from use of products containing prothioconazole.

Freshwater Invertebrates

There were no acute or chronic risk LOC exceedances for freshwater invertebrate species which live primarily in the water column. Therefore, the Agency does not believe that risks to these freshwater invertebrate species are likely to result from use of products containing prothioconazole.

Freshwater Benthic Invertebrates

Based on the chemical/physical characteristics of prothioconazole, the compound has the potential to partition to sediments. Some chronic RQ values (range 0.35 – 3.4, LOC=1.0) exceed the chronic risk LOC when based on the NOAEC of 5.9 µg ai/L of sediment pore water for the midge (*Chironomus riparius*); however, RQ values drop below the LOC when based on the

LOAEC of 66 µg ai/L at which there was a 24% reduction in adult emergence. Therefore, the Agency determined that risks of concern for freshwater benthic invertebrates are unlikely.

Estuarine/Marine Water Column Invertebrates

Both acute and chronic risks of concern were identified for estuarine/ marine invertebrates as a result of prothioconazole use on rice in flooded fields based on maximum labeled application rate. The acute RQ for this scenario is 2.3 (LOC=0.5). The chronic RQ for this scenario is 1.1 (LOC=1.0). However, while rice is a labeled use, there is no reported usage for rice. The RQs for estuarine/marine invertebrates do not exceed the acute or chronic risk LOCs for any other registered use. Moreover, the RQs for rice represent concentrations in the paddy itself or in water discharged from a rice paddy to an adjacent stream or drainage canal. Downstream concentrations may not be accurately represented due to dilution and degradation during travel time away from the point of discharge. Based on this, the likelihood of adverse effects on estuarine/ marine invertebrate species from exposure to water released from rice paddies is expected to be low.

Estuarine/Marine Benthic Invertebrates

For benthic estuarine/marine invertebrates, RQ values range for 0.15 to 1.4 and only exceed the chronic risk LOC for aerial application of prothioconazole to corn based on the non-definitive NOAEC of 13.7 µg a.i./L for the amphipod *Leptocheirus plumulosis*. No adverse effects were detected in the study with the amphipod; therefore, it was not possible to derive a LOAEC from the study. The potential for risk is uncertain.

Aquatic Vascular and Non-Vascular Plants

Non-vascular plant RQs exceeded the LOC of 1.0 for all prothioconazole uses based on maximum application rates (RQs ranged from 0.51-5.5) except for ground application to bushberry. Risks to non-vascular plants were based on a study with marine diatom *Skeletonema costatum* exposed to prothioconazole-desthio, a prothioconazole degradate, where the most sensitive endpoint was reduced yield. Based on this information, the Agency believes that risks to non-vascular aquatic plant species may result from use of products containing prothioconazole.

The RQ values for vascular aquatic plants only exceeded the LOC of 1.0 for use on rice (RQ = 3.9) based on the maximum application rate allowed on the label. Risks to vascular plants were based on a 7-day toxicity test with duckweed (*Lemna gibba*) exposed to prothioconazole-desthio. The most sensitive endpoint was reduced frond number. Risks for aquatic plants do not exceed the LOCs for any other registered use. As mentioned above, there is no reported usage for rice. Based on this information, the Agency does not believe that risks to vascular aquatic plant species are likely to result from use of products containing prothioconazole.

2. Ecological Incidents

EPA reviewed prothioconazole incidents reported to the Incident Data System (IDS) on April 30, 2020 and there were 20 incidents reported from 2009 to 2020. Of the 20 incidents, 17 were listed

with 'possible' certainty, while three were classified as 'unlikely.' Among the 17 incidents with 'possible' certainty, one incident was associated with honey bees and 16 were associated with plants. Six of the 17 incidents were reported to reflect registered uses of products containing prothioconazole at the time of the incident and 3 incidents were reported to reflect misuse of products containing prothioconazole. The legality of use was undetermined in the eight remaining incidents. The 16 plant incidents occurred between 2009 and 2016 and impacted between seven and 525 acres of plants. In the single honey bee incident, hive losses were reported followed the application of PROSARO® 421 SC (19.0% prothioconazole) to a crop; however, investigation of the incident determined that no link could be found between the loss of the bees and pesticides applied in the vicinity of the apiaries. Additionally, no aggregate risks have been reported to the Agency for prothioconazole. The Agency intends to monitor ecological incidents for prothioconazole and will conduct additional analyses if necessary.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for prothioconazole is complete. Although there are exceedances of chronic risk LOC for larval bees, there were no detectable effects at the colony level based on the semi-field studies. While there is one honey bee-related incident reported with a certainty rating of *possible*, in which there was reported hive loss following the application of prothioconazole to wheat, the state's investigation of the incident determined that no link could be found between the loss of the bees and pesticides applied in the vicinity of the apiaries. Given the low magnitude of chronic RQ values based on Tier 1 data and the absence of detectable effects in three colony-level studies, and the results of the incident investigation, no additional Tier II or Tier III data are recommended.

C. Benefits Assessment

Prothioconazole is the only fungicide in the triazolinthiones chemical group within Group 3 of the DMI (DeMethylation Inhibitor) tirazole fungicides as classified by the Fungicide Resistance Action Committee (FRAC).[24] Prothioconazole represents an important mode of action within Integrated Pest Management (IPM) and resistance management programs. As such, its use is important in preserving the effectiveness of rotational fungicides that control economically significant diseases within registered use sites. In sugar beets, prothioconazole is used and recommended as a foliar spray for the management of *Rhizoctonia* spp. stem and crown canker, leaf spot and powdery mildew.[25] It is also recommended to control and/or suppress white mold and Cylindrocladium black rot on peanuts;[26] Stagonospora leaf/glume blotch, Septoria leaf

[24] Fungicide Resistance Action Committee (FRAC). 2021. FRAC Mode of Action (MoA) classification of fungicides. Available at: https://www.frac.info/fungicide-resistance-management/by-fungicide-common-name. [Accessed January 2021].
[25] NDSU (North Dakota State University). 2016. North Dakota Field Crop Plant Disease Management Guide. Available at: https://www.ag.ndsu.edu/extplantpath/publications-newsletters/fungicides/2016-fungicide-guide-full-version/view. [Accessed January 2021].
[26] Abney MR. 2020. Peanut: Peanut Insect Control. In: Georgia Pest Management Handbook. University of Georgia Extension. Available at: https://extension.uga.edu/content/dam/extension/programs-and-services/integrated-pest-management/documents/handbooks/2020-pmh-chapters/Peanut.pdf. [Accessed January 2021]

blotch, tan spot, stripe rust, leaf rust, stem rust and head scab on wheat;[27] frogeye leaf spot and soybean rust on soybeans;[28] common rust, northern leaf blight, and southern rust on corn;[29] and cotton stem blight and boll rot in cotton.[30]

Prothioconazole also represents an important tool for fungal disease management in minor and specialty crops such as blueberries,[31] where it is recommended for mummy berry, powdery mildew, Septoria leaf spot, leaf rust, and Valdensia leaf spot.[32] Prothioconazole is the only available fungicide recommended for the suppression of Valdensia leaf spot on blueberries, an invasive fungal disease which causes early or complete leaf drop in infected blueberry plants so that no flower buds and fruits are produced.[32 33]

For seed treatments, prothioconazole is registered for use on sugar beets, soybeans, peas and beans, barley, buckwheat, corn (sweet, field, pop), millet, oats, proso millet, rice, rye, sorghum, triticale, wheat, alfalfa, and cotton. It is recommended to target and suppress smut, general seed rots, damping off and early season root and foot rots (e.g., *Rhizoctonia, Fusarium*, *Cochliobolus)* in order to improve stand establishment.[34 35]

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[27] Onofre KA, De Wolfe ED. 2020. Foliar Fungicide Efficacy Ratings for Wheat Disease Management 2020. Kansas State University Agricultural Experiment Station and Cooperative Extension Service. Available at: https://www.postrock.k-state.edu/crops/KSUWheatfungicideefficacyratings2020.pdf. [Accessed January 2021].

[28] NCERA-137 (North Central Regional Committee on Soybean Diseases). 2020. Management of Soybean Diseases- Fungicide Efficacy for Control of Soybean Diseases. Available at: https://uofi.app.box.com/s/el4cm2j9oxyt4xvrsdov76dk4px8jw3o. [Accessed January 2021].

[29] CDWG (Corn Disease Working Group). 2020. Management of Corn Diseases- Fungicide Efficacy for Control of Corn Diseases. Available at: https://uofi.app.box.com/s/z7pln89js90bzzw47tdjos9rhj52rd62. [Accessed January 2021].

[30] Hu J. 2018. Cotton Stem Blight and Boll Rot. University of Arizona, College of Agriculture and Life Sciences, Cooperative Extension. Available at: https://extension.arizona.edu/sites/extension.arizona.edu/files/pubs/az1770-2018.pdf. [Accessed January 2021].

[31] Homa K. 2020. Benefits discussion to support prothioconazole (Case Number 7054) EPA's draft human health and/or ecological risk assessments for the registration review (draft risk assessment (EPA-HQ-OPP-205-0474)). The IR-4 Project. Available at: https://www.regulations.gov/docket/EPA-HQ-OPP-2015-0474. [Accessed January 2021].

[32] Annes S, Kornelis G, Tooley B, Calderwood L. 2020. Blueberry Disease Management Guide. Fact Sheet No. 219, UMaine Extension No. 2000. University of Maine Cooperative Extension. Available at: https://extension.umaine.edu/blueberries/factsheets/disease-2/disease-control-for-wild-blueberries/. [Accessed January 2021].

[33] Annes S. 2009. Valdensinia Leaf-spot Disease. University of Maine Cooperative Extension. Available at: https://extension.umaine.edu/blueberries/factsheets/disease/valdensinia-leaf-spot-disease/. [Accessed February 2021].

[34] Onofre KA, De Wolfe ED. 2020. Seed Treatment Fungicides for Wheat Disease Management 2020. Kansas State University Agricultural Experiment Station and Cooperative Extension Service. Available at: https://bookstore.ksre.ksu.edu/pubs/MF2955.pdf. [Accessed February 2021].

[35] UAS (University of Arkansas System). 2021. 2021 Arkansas Plant Disease Control Products Guide. University of Arkansas System, Division of Agriculture, Research and Extension. Available at: https://www.uaex.edu/publications/pdf/mp154/2021/2021-MP154-Entire-Publication.pdf. [Accessed January 2021]

Alternative fungicides to prothioconazole for registered crops include other FRAC group 3 chemistries such as propiconazole, fenbuconazole, flutriafol, metconazole, tebuconazole and tetraconazole.[26 32 30 28 25 27] Other potential alternatives include azoxystrobin, boscalid, flutolanil, fluxapyroxad, fluoxastrobin, penthiopyrad, picoxystrobin, pyraclostrobin, thiophanate methyl and trifloxystrobin, [25 26 27 28 30 32] depending on the target pests being treated. However, prothioconazole is the only available fungicide within the triazolinthione chemical group and represents an important rotational tool for growers as part of an effective IPM and resistance management program.

In nursery production, prothioconazole is considered as the most important fungicide in forest tree seedling production in the southern U.S., as it is currently the only registered pesticide for the control of Fusiform rust *(Cronartium quercuum* f. sp. *fusiforme*) in forest nurseries.[36] Fusiform rust is the most limiting disease in southern pine production.[36] Prothioconazole is also used to effectively treat pitch canker (*Fusarium circinatum*) and Rhizoctonia stem and foliar blight (*Rhizoctonia* sp.).[36 37] Prothioconazole is the only registered fungicide for the treatment of pitch canker and other *Fusarium* spp. diseases in pine and conifer nurseries.[36 37] Prothioconazole alternatives in nursery production for stem and foliar blight control include iprodione, thiophanate-methyl, fludioxonil, and azoxystrobin;[38] however, these have been proven to be less effective than prothioconazole.[39] No registered alternatives are currently available for Fusiform rust or pitch canker in forest nurseries.[36 37]

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

The Agency has reviewed the uses, risks, and benefits of prothioconazole. As discussed in Section III of this document, EPA identified potential risks to occupational workers, non-vascular aquatic plants, and mammals. EPA has also identified the benefits of prothioconazole in preventing certain fungal diseases in crops such as corn, wheat, soybeans, sugar beets, dried shelled peas and beans, peanuts, cotton, blueberries and in forest nurseries.

The Agency has weighed the benefits of prothioconazole against the potential occupational handler risks and has determined that application rate reduction, prohibition of certain application methods, and the implementation of activity specific re-entry prohibitions are

[36] Starkey T. 2020. Alabama Forest Nursery Consultant. Per communication between U.S. Department of Agriculture, Office of Pest Management Policy (USDA, OPMP) and Tom Starkey.
[37] Cram M. 2020. U.S. Forest Service (USFS) Region 8, Forest Health Protection. Per communication between U.S. Department of Agriculture, Office of Pest Management Policy (USDA, OPMP) and USFS.
[38] Carey WA, McQuage K. 2004. Control of Rhizoctonia Blight by fungicides and fumigation. Research Report 04-3. Auburn University, Southern Forest Nursery Management Cooperative.
[39] Starkey TE, Enebak SA, McQuage K, Barfield K. 2013. Control of Rhizoctonia foliar blight in forest seedling nurseries: a 3-year study. In: Haase DL, Pinto JR, Wilkinson KM, technical coordinators. National Proceedings: Forest and Conservation Nursery Associations—2012. Fort Collins (CO): USDA Forest Service, Rocky Mountain Research Station. Proceedings RMRS-P-69. 11-16. Available at: http://www.fs.fed.us/rm/pubs/rmrs_p069.html. [Accessed January 2021]

appropriate to ensure that prothioconazole continues to meet the FIFRA standard. Additionally, the Agency has weighed the benefits of prothioconazole against the potential ecological risks and has determined that updated advisory spray drift language, treated seed language, and an updated surface water advisory language are appropriate to ensure that prothioconazole continues to meet the FIFRA standard. EPA is also proposing to update and standardize the treated seed language to adhere to the Agency's labeling best practices and other labeling updates, such as resistance management language, consistent with those which are being required for other pesticides in registration review. The technical registrant has agreed to the label changes outlined in Appendix B.

1. Label Mitigation: Application Rate Reduction for Corn Seed Treatment

In the PID, the Agency proposed adding coveralls to mitigate potential risks to occupational handlers performing corn seed treatment. Requiring an additional layer of PPE (coveralls) for occupational workers performing multiple activities during seed treatment of corn seeds would adequately mitigate the handler risks identified in the HHRA at the current maximum application rate of 3.83 fl oz a.i. /100 lbs seed. However, since the PID was issued the Agency has revised the mitigation strategy and has determined that the maximum corn seed application rate could be reduced from 3.83 fl oz a.i. /100 lbs seed to 2.0 fl oz a.i. /100 lbs seed in lieu of the PPE mitigation. Reducing the maximum application rate would increase the total MOE for the multiple activities scenario to an acceptable level and would adequately mitigate risks to occupational workers without the need for additional PPE. This mitigation approach was proposed by the technical registrant in response to mitigation proposed in prothioconazole PID.

Based on information provided by the technical registrant, the recommended range of application rates for commercial application to corn seeds is between 0.25 fl oz a.i. /100 lbs seed and 1 fl oz a.i. /100 lbs seed. The upper limit of this range provides control and suppression of early seedling diseases caused by *Fusarium spp.* and *Rhizoctonia solani.* under conditions of high disease pressure and adverse environmental conditions.[40] Therefore, it is unlikely that reducing the maximum application rate from 3.83 fl oz/100 lbs seed to 2.0 fl oz/100 lbs seed would have adverse impacts on efficacy, users, or handlers.

The reduction of the maximum rate of prothioconazole applied to corn seed will also result in a reduction in the potential exposure to mammals that consume the seed. For mammals feeding exclusively on corn in a treated field, this would significantly increase the number of seeds required to elicit the adverse effects. For mammals eating corn as a portion of their overall diet, the reduced exposure might cause overall exposure to be below the level of concern.

2. Label Mitigation: Prohibition of Application Methods

There are potential occupational handler risks of concern for occupational workers mixing, loading, and applying liquids using mechanically pressurized handguns to orchards/vineyards,[41]

[40] Comment submitted by Bayer CropScience LP, EPA-HQ-OPP-2015-0474-0052. Available at www regulations.gov

[41] Bushberry subgroup 13-07B, Low growing berry subgroup, except strawberry subgroup 13-07H

field crops,[42] and nursery ornamentals (pine and conifer seedlings).[43] Current label requirements specify that mixer/loader/applicators of prothioconazole must wear a single layer of clothing and chemical resistant gloves when using this application equipment. The combined dermal and inhalation risks of concern for orchards/vineyards and field crop scenarios are driven by the dermal risks and the combined risks of concern for workers in the nursery ornamentals scenario are driven by the inhalation risks.

In order to mitigate the identified risks to occupational handlers, EPA has determined that it is necessary to prohibit the use of mechanically pressurized handguns when applying products containing prothioconazole to orchards/vineyards, field crops, and nursery ornamentals.

Terminating this type of application equipment will reduce potential risks to the handler. The impacts of this prohibition are likely to be small as applications by hand are generally rare in most cropping systems. Information from USDA indicated that mechanically pressurized handgun use is rare in nurseries.[44]Furthermore, information provided by the Auburn University Southern Forest Nursery Management Cooperative indicates that nurseries do not use handheld equipment when applying prothioconazole and this mitigation strategy would not have impacts on this industry.[45]

3. Label Mitigation: Implement Crop-Specific Restricted Entry Interval

The Agency identified occupational post-application dermal risks of concern for sweet corn hand harvesting and detasseling. All associated end-use products containing prothioconazole currently require 12-hour REIs. The Agency determined that prohibiting re-entry to treated sweet corn fields for 24 hours after application of products containing prothioconazole is necessary to protect post-application workers. This prohibition adequately mitigates the risks of concern. Impacts are not anticipated to result from implementing a 24-hour REI.

4. Label Mitigation: Spray Drift Management

The Agency determined that updates to the advisory spray drift management language to prothioconazole labels are needed to reduce off-target spray drift and consistently protect against a baseline level of spray drift across all prothioconazole products.

Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the Agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk

[42] Cucurbit Vegetables (Crop Group 9), Corn, sweet, Garbanzos (including chickpeas); Lentils
[43] Shortleaf loblolly, Slash, Longleaf and other pines, other conifers, other hardwoods
[44] Starkey T. 2020. Alabama Forest Nursery Consultant. Per communication between U.S. Department of Agriculture, Office of Pest Management Policy (USDA, OPMP) and Tom Starkey.
[45] Wernsman, D., 2021. Federal Registrations Manager at Bayer Crop Science LP. Personal communication received via email to EPA on July 19, 2021. The Auburn University Southern Forest Nursery Management Cooperative (SFNMC) assisted Bayer with obtaining the pine nursery registration for prothioconazole. Bayer consulted with SFNMC regarding potential impacts of prohibiting hand held uses of prothioconazole in forest nurseries. SFNMC indicated that at no time do nurseries use a hand wand application for prothioconazole and that this mitigation strategy would have no impacts on the use in forest nurseries.

to listed species whose range and/or critical habitat co-occur with the use of prothioconazole. The specific label language for drift management is detailed in Appendix B.

5. Label Mitigation: Standardize Treated Seed Language

EPA determined that standardizing seed handling language across prothioconazole products that are labeled for commercial seed treatment is needed. Labels for prothioconazole seed treatment products and information provided on bags of treated seed currently include best management practices for handling treated seed; however, the language is not uniform across labels. Standardization of seed treatment language may also limit exposure to non-target animals. EPA determined that all prothioconazole seed treatment labels need to include the following statements:[46]

- Store treated seed away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seeds.
- When opening this bag or loading/pouring the treated seed/seed-pieces, wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves (additional coveralls required for treatment of corn seeds).
- Treated seeds exposed on the soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends).
- Dispose of all excess treated seed by burying seed away from bodies of water.
- Do not contaminate bodies of water when disposing of planting equipment wash water.
- Plant treated seed into the soil to the recommended minimum depth or greater to minimize exposure.
- Do not plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting, additional incorporation may be required to thoroughly cover exposed seeds.
- Dispose of seed packaging or containers in accordance with local requirements.
- Excess treated seed may be used for ethanol production if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.
- Required Dye Statement (if applicable): Seed treated with this product must be visually identifiable from untreated seed by the use of an approved colorant or dye to prevent accidental use of treated seed as food for humans or feed for animals. Refer to 21 CFR, § 2.25. Any colorant or dye added to treated seed must be cleared for use in accordance with 40 CFR, § 153.155(c).

The purpose of standardizing the treated seed language is to encourage the adoption of best management practices when handling and planting prothioconazole-treated seeds and will reduce the exposure of birds and mammals to treated seeds on the field. Covering or collecting spilled seed and burying excess seed within the field will reduce the likelihood that animals will find and consume treated seeds. Disposing of excess seeds and equipment wash water away from water bodies, which tend to be gathering points for birds and mammals, decreases the chance of contaminating those water bodies with prothioconazole residues and the chance that animals will discover and consume treated seeds while visiting a body of water. Ensuring that treated seeds

[46] For specific label language, see Appendix B.

are distinguishable from unaltered seeds helps to prevent accidental use of treated seeds for food for humans or feed for animals. These requirements reinforce best management practices and are unlikely to result in economic impacts on the use of seed treatments or of treated seed.

6. Label Mitigation: Environmental Hazard Statements

Due to the fate properties of prothioconazole, the Agency is has determined that the addition of surface water advisory statements on prothioconazole product labels are necessary.[47] These statements are not found on current prothioconazole labels. However, no potential impacts to growers are expected to result from the surface water advisory statement language outlined in this decision.

Additionally, the Agency identified necessary updates to the ground water advisory statement currently on prothioconazole labels, consistent with Chapter 8 of the Label Review Manual.[48] EPA determined that, in addition to prothioconazole-desthio, a second degradate of prothioconazole (1,2,4-triazole) is relevant for ground water contamination. 1,2,4-triazole is a degradate of prothioconazole and is mobile, persistent, and has been detected in non-targeted groundwater monitoring at up to 5.8 µg/L.[49] The update to the ground water advisory statement does not fundamentally change the advisory statement, and simply indicates that multiple degradates are known to leach through soil into groundwater. No potential impacts to growers are expected to result from the groundwater advisory language outlined in this decision. The text of the environmental hazard statements can be found in Appendix B.

7. Label Mitigation: Fungicide Resistance Management

The Agency determined that adding resistance-management language to prothioconazole labels[50] is necessary to provide pesticide users with easy access to important information to help maintain the effectiveness of useful pesticides.[51] Consistent with EPA's Pesticide Registration Notice (PRN) on general pesticide resistance management,[52] EPA intends to implement pesticide resistance measures for existing chemicals during registration review and for new chemicals and new uses at the time of registration. To combat pesticide resistance, resistance management experts recommend using pesticides with different chemical modes (or mechanisms) of action against the same target pest population as part of IPM programs. This approach may prevent or delay target pest populations from developing resistance to a particular mode (or mechanism) of action without resorting to increased rates and frequency of application, possibly prolonging the useful life of pesticides.

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[47] For specific label language, see Appendix B.
[48] Label Review Manual, https://www.epa.gov/pesticide-registration/label-review-manual.
[49] 1,2,4-Triazole, Triazole Alanine, & Triazole Acetic Acid Drinking Water Exposure Assessment for Registration Review, https://www regulations.gov/document/EPA-HQ-OPP-2015-0401-0018
[50] For specific label language, see Appendix B.
[51] Pesticide resistance is the ability of portions of a pest population to tolerate or survive otherwise lethal doses of a pesticide through genetic or behavioral changes. EPA considers increased pesticide resistance an adverse effect that can drive increased use of pesticides. For more details, see PRN 2017-1 and PRN 2017-2, available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.
[52] PRN 2017-1, "Guidance for Pesticide Registrants on Pesticide Management Labeling" (Aug. 24, 2017), available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.

Adding this language will provide pesticide users with easy access to important information on maintaining the effectiveness of pesticides—including prothioconazole—thereby preserving the benefits of prothioconazole and other useful pesticides.[3] No potential impacts to growers are expected to result from the fungicide resistance management language outlined in this decision.

B. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. EPA has conducted assessments of risks to farmworkers who handle prothioconazole or may be exposed to prothioconazole when working in treated fields and are mitigating the risks identified with this ID. EPA has also evaluated the risks to people living adjacent to treated fields, which may include many farmworker families, and found no risks of concern from currently registered uses of prothioconazole. The Agency sought information during the public comment period for the PID on any other groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to prothioconazole compared to the general population or who may otherwise be disproportionately affected by the use of prothioconazole as a pesticide. EPA did not receive any comments concerning environmental justice at that time. The Agency welcomes information on any other groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to prothioconazole compared to the general population or who may otherwise be disproportionately affected by the use of prothioconazole as a pesticide.

C. Tolerance Actions

The Agency plans to exercise its FFDCA authority to modify the tolerances for prothioconazole, to reflect Organization for Economic Cooperation and Development (OECD) rounding class practices and to harmonize with CODEX, where applicable, as summarized in Table 1, below.

Table 1: Summary of Tolerance Actions

Prothioconazole 40 CFR § 180.626: Summary of Anticipated Tolerance Actions			
Commodity	**Established Tolerance (ppm)**	**Anticipated Tolerance (ppm)**	**Comment**
Berry, low growing, except strawberry, subgroup	0.20	0.2	To conform to OECD rounding class practices
Bushberry, subgroup 13-07B	2.0	2	
Cotton, gin byproducts	4.0	4	
Grain, cereal, forage, fodder and straw, group 16, except soybean and rice, forage	8.0	8	

[3] For a detailed discussion of prothioconazole's benefits, see Section III.C., above.

Prothioconazole 40 C.F.R. § 180.626: Summary of Anticipated Tolerance Actions			
Commodity	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice, hay	7.0	7	
Grain, cereal, forage, fodder and straw, group 16, except sorghum, straw	5.0	5	
Pea and bean, dried shelled, except soybean, subgroup 6c	0.9	1	To harmonize with Codex
Rice, hulls	0.90	0.9	To conform to OECD rounding class practices.
Soybean, seed	0.15	0.2	To harmonize with Codex
Beet, sugar, roots	0.25	0.3	
Vegetable, cucurbit, crop group 9	3.0	3	To conform to OECD rounding class practices.
Cattle meat byproducts	0.2	0.3	To harmonize with Codex
Goat meat byproducts	0.2	0.3	
Horse meat byproducts	0.2	0.3	
Sheep meat byproducts	0.2	0.3	

ppm=parts per million (equivalent to milligrams per kilogram, mg/kg)

D. Interim Registration Review Decision

The Agency is issuing this ID in accordance with 40 CFR §§ 155.56 and 155.58. The Agency has made the following interim decision: (1) no additional data are required, and, (2) prothioconazole does not meet the registration standard without the changes to the affected registrations and their labeling outlined in Sections IV.A-B and Appendices A and B.

The Agency conducted a detailed draft human health risk assessment and a detailed draft ecological risk assessment. EPA has reviewed the potential risks and has weighed them against the benefits of the continued use of prothioconazole in developing this interim decision. In those risk assessments, EPA observed risks to continuing to register prothioconazole.

EPA has determined that continuing to register prothioconazole provides significant benefits. EPA identified the benefits of prothioconazole in preventing certain fungal diseases in corn, wheat, soybeans, sugar beets, dried shelled peas and beans, and peanuts.

Potential human health risks of concern were identified for occupational workers performing corn seed treatment, mixing, loading and applying liquids using mechanically pressurized handguns in some scenarios, and hand harvesting and detasseling sweet corn. The Agency has determined that application rate reduction for corn seed treatment, prohibition of the use of mechanically pressurized handguns, and an activity specific REI for hand-harvest and detasseling of sweet corn are needed to address these risks. Implementation of these mitigation measures would adequately address the human health risks of concern without compromising the benefits of the use.

Potential ecological risks of concern were identified for non-vascular aquatic plants and mammals. To address these risks, the Agency is proposing spray drift management language, ground and surface water advisory statements, and standardization of treated seed language.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[54] Here, EPA finds that prothioconazole does not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A and Appendices A and B. Due to the risks to occupational handlers and several ecological taxa, the FIFRA risk-benefit standard is not met with current label restrictions.

EPA has determined that there is no human dietary risk from registered uses of prothioconazole that is inconsistent with the FFDCA safety standard. Taking into consideration the available information on toxicity and exposure, EPA assessed prothioconazole's potential aggregate risks, including dietary (food and water) and non-occupational residential exposures, and found no risks exceeding the Agency's levels of concern.[55]

EPA has determined that there is a reasonable certainty that no harm will result from aggregate exposure to prothioconazole, including all anticipated dietary exposures and all other exposures for which there is reliable information. Therefore, prothioconazole's residues do not present human dietary risk and EPA intends to leave the tolerances in place (with minor modifications anticipated), because EPA's analysis indicates those tolerances are safe.

In this ID, the Agency is not making any human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of prothioconazole. Similarly, the Agency is not making a complete federally listed threatened/endangered species finding, though the necessary mitigation is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range or designated critical habitat co-occur with the use of prothioconazole. The Agency will complete a listed-species assessment and any necessary Endangered Species Act (ESA) Section 7 consultation with the Services and make an EDSP determination before issuing a final registration review decision for prothioconazole.

E. Data Requirements

EPA does not anticipate calling in additional data for prothioconazole's registration review.

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[54] 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); *see also* 7 U.S.C. §§ 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA's risk-benefit standard] **and** "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]").

[55] *Prothioconazole: Human Health Draft Risk Assessment for Registration Review* (May 15, 2020). EPA-HQ-OPP-2015-0474-0027 available on www.regulations.gov

V. NEXT STEPS AND TIMELINE

A Federal Register Notice will announce the availability of the prothioconazole ID. A final registration review decision for prothioconazole will only be made after EPA completes (1) an endangered species determination and any necessary consultation with the Services, and (2) an EDSP determination.

Registrants must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of the amended product labels within 60 days after the announcement of this ID in the *Federal Register*. Two copies for each label must be submitted, a clean copy and an annotated copy with changes. In order for the application to be processed, registrants must include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment satisfies the requirements of the prothioconazole Interim Registration Review Decision and EPA regulations at 40 C.F.R. Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the prothioconazole Interim Registration Review Decision and 40 C.F.R. Section 152.44, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Within the required timeframe, registrants must submit the required documents to the Re-evaluation section of EPA's Pesticide Submission Portal (PSP), which can be accessed through EPA's Central Data Exchange (CDX) at https://cdx.epa.gov/. Registrants may instead send paper copies of their amended product labels, with an application for a fast-track, Agency-initiated non-PRIA label amendment to Rachel Eberius at one of the following addresses, so long as the labels and application are submitted within the required timeframe:

VIA US Mail
USEPA Office of Pesticide Programs
Pesticide Re-evaluation Division
Mail Code 7508P
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

Appendix A: Summary of Actions for Prothioconazole

Registration Review Case #: 7054
PC Code: 113961
Chemical Type: Fungicide
Chemical Family: Conazole fungicide group (triazoles)
Mode of Action: De-Methylation Inhibitors

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Actions	Comment
• Occupational handler conducting multiple activities during corn seed treatment	• Residues at site of treatment	• Dermal	• Sub-Chronic	• Developmental	• Rate reduction	Reduce the maximum application rate for all corn seed treatment
• Occupational handlers during loading and applying with mechanically pressurized handguns at commercial	• Residues at site of treatment • Air	• Inhalation • Dermal	• Sub-Chronic	• Developmental	• Application equipment prohibition	Prohibit use of mechanically pressurized handguns for orchards and vineyards, typical field crops, and nursery ornamentals
• Occupational post-application worker engaged in hand harvest or detasseling of sweet corn	• Residues on site of treatment	• Dermal	• Sub-Chronic	• Developmental	• Lengthen REI for sweet corn activities to 24 hours	Prohibition of reentry in sweet corn fields for hand harvesting and hand detasseling activities
• Mammals	• Residues	• Ingestion	• Chronic	• Growth and Reproduction	• Update advisory spray drift language • Standardize seed treatment language for commercial production of seeds	

Appendix B: Necessary Labeling Changes for Prothioconazole Products

Description	Label Language for Prothioconazole Products	Placement on Label
	End Use Products	
Mode of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP**" in the second column • Include the **MODE/MECHANISM/SITE OF ACTION CODE** in the third column (for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action; for Herbicides this is **SITE OF ACTION**) • Include the type of pesticide (*i.e.*, FUNGICIDE) in the fourth column. **PROTHIOCONAZOLE** | **GROUP** | **3** | **FUNGICIDE**	Front Panel, upper right quadrant: All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Reduced Maximum Application Rate for all products allowing seed treatment to corn seeds	The labels of all end-use products with corn seed application must be revised to bear the following application rates under the Crop Specific Directions for Use Section for Corn: A maximum application rate of 2.0 fl oz a.i./100 lbs seed	To the Crop Specific Directions and Restrictions for Corn
Prohibition of Application Methods	• "Do not apply prothioconazole with mechanically pressurized handgun equipment to orchards or vineyards (Bushberry subgroup 13-07B, Low growing berry subgroup, except strawberry subgroup 13-07H), field crops (Cucurbit Vegetables (Crop Group 9) Corn, sweet, Garbanzos (including chickpeas), Lentils) or nursery (pine and conifer seedlings (Shortleaf loblolly, Slash, Longleaf and other pines, other conifers, other hardwoods)."	Directions for Use under Restrictions Header

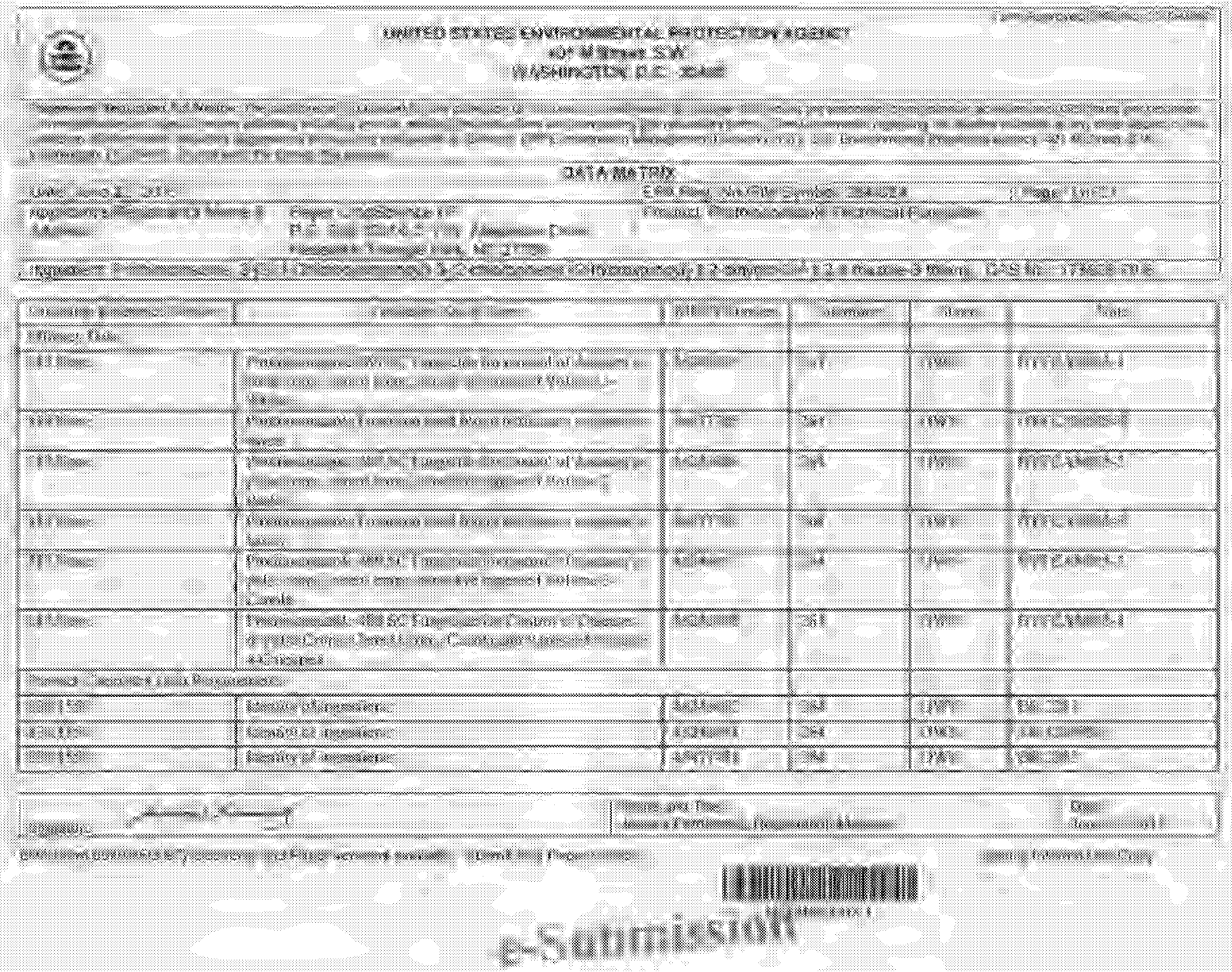
Description	Label Language for Prothioconazole Product	Placement on Label
Resistance management for fungicides	Include resistance management label language for fungicides from PRN 2017-1 (http://www2.epa.gov/pesticide-registration/prn-2017-1-general-resistance-management-labeling)	Directions for Use, prior to directions for specific crops
Restricted-Entry Interval statement for the Agricultural Use Requirements Box for products with multiple crops with different REIs	Registrants, REPLACE current label language with the following: • "Do not enter or allow workers to enter during the restricted-entry interval (REI) of 12 hours. Some crops have longer crop-specific REIs. Crop-specific REIs are listed in the Directions for Use section associated with the crop"	Within the Agricultural Use Requirements Box
Restricted-Entry Interval for sweet corn	Include crop-specific REI for sweet corn: "Sweet Corn: The REI is 24 hours."	Directions for Use under the appropriate crop specific directions
Seed handling language for products that allow for commercial seed treatment	**"Seed Bag Label Requirements** The Federal Seed Act requires that containers containing treated seeds shall be labeled with the following statements: • This seed has been treated with (INSERT PRODUCT NAME), a fungicide containing prothioconazole. • Do not use treated seed for feed, food, or oil purposes. The U.S. Environmental Protection Agency requires the following statements on containers containing seed treated with prothioconazole: • Store treated seed away from food and feedstuffs. • Do not allow children, pets, or livestock to have access to treated seeds. • When opening the bag or loading/planting the treated seed/seed-pieces, wear long sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves (additional coveralls required for treatment of corn seeds). • Treated seeds exposed on the soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends). • Dispose of all excess treated seed by burying seed away from bodies of water. • Do not contaminate bodies of water when disposing of planting equipment wash water. • Plant treated seed into the soil to the recommended minimum depth or greater to minimize exposure.	Directions for Use under Seed Bag Tag and Directions for Use for treating seed on product label

Description	Label Language for Prothioconazole Products	Placement on Label
	• DO NOT plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting; additional incorporation may be required to thoroughly cover exposed seeds. • Dispose of seed packaging or containers in accordance with local requirements. • Excess treated seed may be used for ethanol production if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice. **REQUIRED DYE STATEMENT (if applicable)** On Pesticide label: Seed treated with this product must be visually identifiable from untreated seed by the use of an approved colorant as dye to prevent accidental use of treated seed as food for humans or feed for animals. Refer to 21 CFR § 2.25. Any colorant or dye added to treated seed must be cleared for use in accordance with 40 CFR § 153.155(c)."	
Surface Water Advisory	"This product may impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of prothioconazole and degradates from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours."	Environmental Hazards
Ground Water Advisory Update	"Degradates of prothioconazole are known to leach through soil into groundwater under certain conditions as a result of label use. These chemicals may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow."	Environmental Hazards
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** *(note to registrants: remove if ground boom is prohibited on product label.)*	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Label Language for Prothioconazole Products	Placement on Label
	• Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** *(note to registrants: remove if aerial application is prohibited on product labels)* • Adjust Nozzles – Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** *(note to registrants: remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** *(note to registrants: remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.	

Description	Label Language for Prothioconazole Product	Placement on Label
	WIND Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applications need to be familiar with local wind patterns and terrain that could affect spray drift."	
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **Handheld Technology Applications** • Take precautions to minimize spray drift.	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Exhibit 11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WASHINGTON, D.C. 20460

DATA MATRIX

Date: June 22, 2015		EPA Reg. No./File Symbol: 264-824	Page 2 of 28
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1600	Description of Materials	46246002	264	OWN	BR 2281
830.1600	Description of Materials	46246001	264	OWN	1401200950
830.1620	Description of Production Process	46246002	264	OWN	BR 2281
830.1620	Description of Production Process	46246001	264	OWN	1401200950
830.1620	Description of Production Process	46477401	264	OWN	BR 2383
830.1650	Description of Formulation Process	46246002	264	OWN	BR 2281
830.1650	Description of Formulation Process	46246001	264	OWN	1401200950
830.1670	Formulation of Impurities	46246002	264	OWN	BR 2281
830.1670	Formulation of Impurities	46246001	264	OWN	1401200950
830.1700	Preliminary Analysis	46246002	264	OWN	BR 2281
830.1700	Preliminary Analysis	46246001	264	OWN	1401200950
830.1700	Preliminary Analysis	46477401	264	OWN	BR 2383
830.1750	Certified limits	46246002	264	OWN	BR 2281
830.1750	Certified Limits	46246001	264	OWN	1401200950
830.1800	Analytical Method	46246002	264	OWN	BR 2281
830.1800	Analytical Method	46246001	264	OWN	1401200950
830.1900	Submittal of samples	46246002	264	OWN	BR 2281
830.1900	Submittal of samples	46246001	264	OWN	1401200950

Signature	Name and Title	Date
Jessica Fernandez	Jessica Fernandez, Registration Manager	June 22, 2015

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Bayer CropScience LP [illegible]

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[illegible]	Corrosion characteristics	[illegible]	[illegible]	[illegible]	[illegible]

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DATA MATRIX

Date: June 22, 2015		EPA Reg. No./File Symbol: 264-824	Page 4 of 28
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6320	Corrosion characteristics	46246001	264	OWN	1401200950
830.6321	Dielectric breakdown	46246003	264	OWN	BR 2282
830.6321	Dielectric breakdown	46246001	264	OWN	1401200950
830.7000	pH	46246003	264	OWN	BR 2282
830.7000	pH	46246001	264	OWN	1401200950
830.7050	UV/Visible absorption	46246003	264	OWN	BR 2282
830.7050	UV/Visible absorption	46246001	264	OWN	1401200950
830.7100	Viscosity	46246003	264	OWN	BR 2282
830.7100	Viscosity	46246001	264	OWN	1401200950
830.7200	Melting point	46246003	264	OWN	BR 2282
830.7200	Melting point	46246001	264	OWN	1401200950
830.7220	Boiling point	46246003	264	OWN	BR 2282
830.7220	Boiling point	46246001	264	OWN	1401200950
830.7300	Density, bulk-density, or specific gravity	46246003	264	OWN	BR 2282
830.7300	Density, bulk-density, or specific gravity	46246001	264	OWN	1401200950
830.7370	Dissociation constant	46246003	264	OWN	BR 2282
830.7370	Dissociation constant	46246001	264	OWN	1401200950
830.7520	Particle size, fiber length, and diameter distribution	46246003	264	OWN	BR 2282

Signature	Name and Title	Date
Jessica Fernandez	Jessica Fernandez, Registration Manager	June 22, 2015

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Date: June [illegible] 2015 | EPA Reg. No./File Symbol: [illegible] | Page [illegible]

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 | Product: [illegible]

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No. [illegible]

Guideline Reference Number	Guideline Study Name	MRID Number	Selection	Status	Note
[illegible]	[illegible]	[illegible]	[illegible]	OWN	[illegible]
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DATA MATRIX

Date: June 22, 2015	EPA Reg. No./File Symbol: 264-824	Page 9 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.None	Environmental Fate and Ecotox Risk Assessment Nursery, Rice, and Seed Treatment Uses	48526701	264	OWN	US0196
Ecological Effects Data Requirements					
850.1010	Invertebrates toxicity – 480 SC	46246009	264	OWN	HBF/DM 212
850.1010	Invertebrates toxicity - JAU	46246010	264	OWN	200514
850.1010	Invertebrates toxicity - SXX	46246011	264	OWN	HBF/DM 95
850.1010	Invertebrates toxicity – S-Methyl	46246012	264	OWN	DOM 21055
850.1010	Invertebrates toxicity – SXX	46246013	264	OWN	200985
850.1025	Estuarine/marine tox. mollusk – JAU	46246014	264	OWN	110956
850.1025	Method validation marine studies – JAU	46246015	264	OWN	110957
850.1035	Estuarine/marine tox. shrimp - JAU	46246016	264	OWN	110983
850.1035	Estuarine/marine tox. shrimp – SXX	46246017	264	OWN	110979
850.1075	Fish toxicity trout – JAU	46246018	264	OWN	DOM 99076
850.1075	Fish toxicity trout – 480 SC	46246019	264	OWN	200193
850.1075	Fish toxicity trout – SXX	46246020	264	OWN	FF-298
850.1075	Fish toxicity trout – S-Methyl	46246021	264	OWN	DOM 21047
850.1075	Fish toxicity bluegill LC50 – JAU	46246022	264	OWN	DOM 99090
850.1075	Fish toxicity bluegill – 480 SC	46246023	264	OWN	200599

Signature	Name and Title	Date
Jessica Fernandez	Jessica Fernandez, Registration Manager	June 22, 2015

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DATA MATRIX

Date: June 22, 2015		EPA Reg. No./File Symbol: 264-824	Page 11 of 28
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian analytical method – SXX	46246041	264	OWN	110161
850.2300	Avian reproduction, quail – JAU	46246042	264	OWN	259842
850.2300	Avian reproduction, quail – SXX	46246043	264	OWN	BAR/REP006
850.2300	Avian reproduction, duck – JAU	46246044	264	OWN	259919
850.2300	Avian reproduction, duck – SXX	46246045	264	OWN	110617
850.3020	Acute toxicity honey bee – 480 SC	46246046	264	OWN	18351035
850.3020	Parasitoid *Aphidius rhopalosiphi* – 480 SC	46246047	264	OWN	18352002
850.3020	Acute toxicity honey bee – JAU	46246048	264	OWN	IBA 64051
850.4000	Non-target plant testing – 480 SC	46246049	264	OWN	200951
850.4100	Seedling emergence, Tier 1 – 480 SC	46246049	264	OWN	200951
850.4150	Vegetative vigor, Tier 1 – 480 SC	46246049	264	OWN	200951
850.4000	Non-target plant testing – 480 SC	46246050	264	OWN	200952
850.4225	Seedling emergence, Tier 2 – 480 SC	46246050	264	OWN	200952
850.4250	Vegetative vigor, Tier 2 – 480 SC	46246050	264	OWN	200952
850.4400	Aquatic plant growth, duckweed – JAU	46246101	264	OWN	200488
850.4400	Aquatic Plant Growth, duckweed – 480 SC	46246102	264	OWN	200672
850.4400	Aquatic Plant Growth, bluegreen algae – JAU	46246103	264	OWN	200497
850.4400	Aquatic plant growth – SXX	46246104	264	OWN	200469

Signature	Name and Title	Date
Jessica Fernandez	Jessica Fernandez, Registration Manager	June 22, 2015

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Date: [illegible]	EPA Reg. No./File Symbol: [illegible] — Page [illegible]
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide
Ingredient: Prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No. [illegible]	

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Signature: [signature]	Name and Title: [illegible] Regulatory Manager	Date: [illegible]

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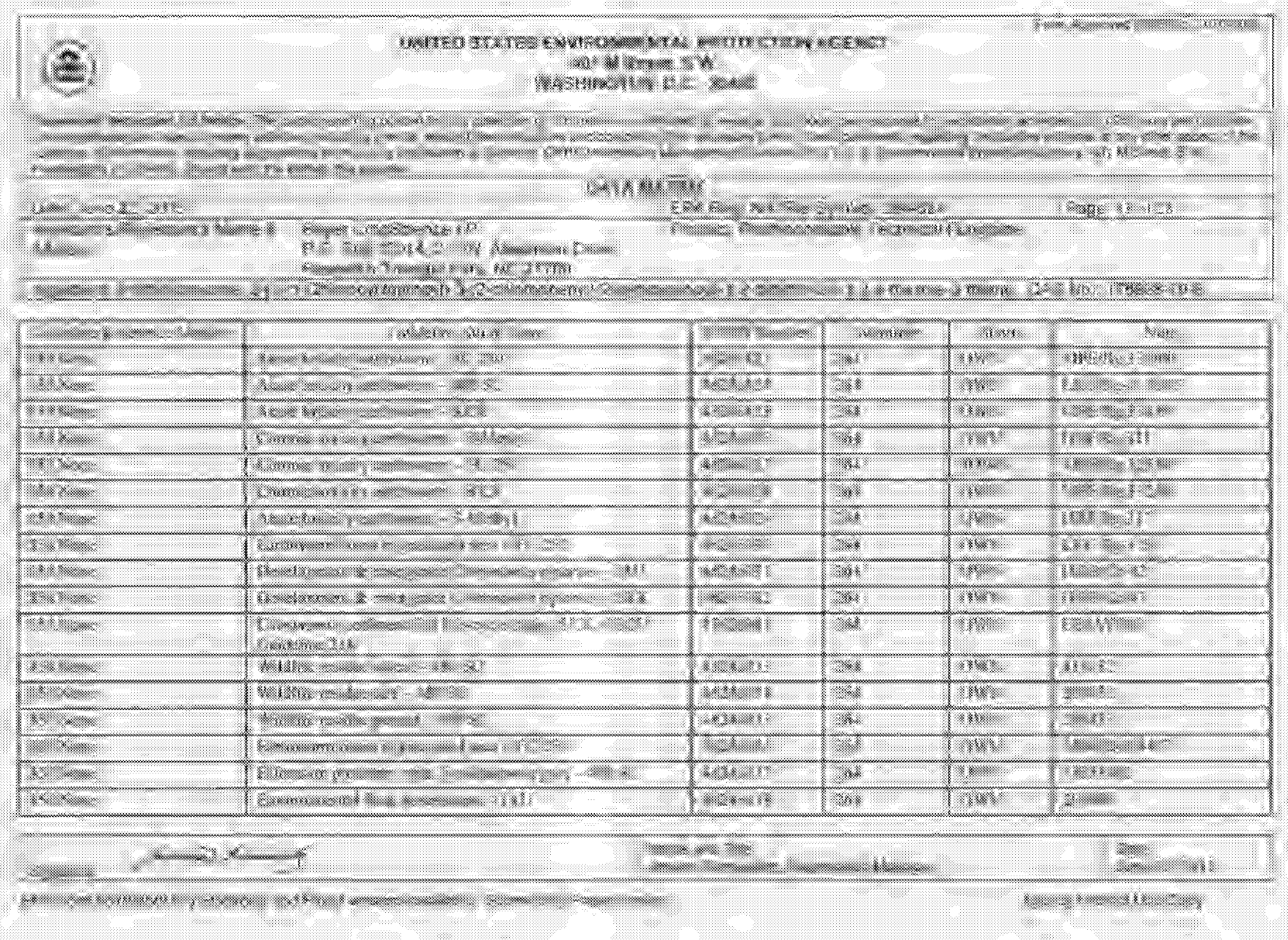

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Date: June 22, 2015		EPA Reg. No./File Symbol: 264-824	Page 16 of 28
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1360	Method multi-residue	46246210	264	OWN	200480
860.1380	Storage stability in crop matrices (6-month data)	46246211	264	OWN	200824
860.1380	Storage stability in crop deficiency study	46477701	264	OWN	201262
860.1380	Storage Stability in crops	47408201	264	OWN	RAJAY016
860.1380	Storage Stability wildlife residue trials – JAU & SXX	46246139	264	OWN	MR-354/01
860.1380	45-day fat storage stability data	47107801	264	OWN	RAJAY040
860.1380	Storage Stability -45 months	48938301	264	OWN	US0312
860.1380	Storage stability triazole	47606601	US Triazole Task Force	Member	RAJAY006
860.1480	Feeding study, cattle – JAU	46246213	264	OWN	200715
860.1480	Feeding study, cattle – SXX	46246214	264	OWN	MR-535/00
860.1480	Feeding study, poultry – JAU	47492801	264	OWN	RAJAL001
860.1500	Crop field study, barley	46246220	264	OWN	200806
860.1500	Crop field study, blueberry	48803301	264	OWN	M-428253-01-1
860.1500	Crop field study, canola	46246215	264	OWN	200464
860.1500	Crop field study, corn	47521901	264	OWN	RAJAP004
860.1500	Crop field study, corn ULV	48116901	264	OWN	RAJAP020-1
860.1500	Crop field study, corn seed treatment	48516202	264	OWN	RA-2567/07

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Jessica Fernandez	Jessica Fernandez, Registration Manager	June 22, 2015

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Date: June 22, 2015	EPA Reg. No./File Symbol: 264-824	Page 17 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Crop field study, corn seed treatment	48516203	264	OWN	RA-6220/06
860.1500	Crop field study, corn seed treatment	48516204	264	OWN	RA-2568/07
860.1500	Crop field study, corn seed treatment	48516205	264	OWN	RA-2621/06
860.1500	Crop field study, cotton	49533302	264	OWN	M-524431-01-1
860.1500	Crop field study, cranberry	48803302	264	OWN	M-428331-01-1
860.1500	Crop field study, cucurbit vegetables	48803303	264	OWN	M-428931-01-1
860.1500	Crop field study, peanuts	46246217	264	OWN	200508
860.1500	Crop field study, peanuts – bridging study (seed, soil, foliar)	47214701	264	OWN	RAJAY035
860.1500	Crop field study, peas & beans, dried	46246221	264	OWN	200956
860.1500	Potato – EU seed treatment	48024903	264	OWN	RA-2569/05
860.1500	Potato – EU seed treatment	48024904	264	OWN	RA-2604/05
860.1500	Crop field study, rice	46246216	264	OWN	200468
860.1500	Sorghum – TRR seed treatment	49531301	264	OWN	M-508603-01-1
860.1500	Crop field study, soybean	46841001	264	OWN	RAJAY026
860.1500	Soybean, Dried Shelled Peas and Beans – Position paper	49533304	264	OWN	MEJAY007-3
860.1500	Crop field study, sugar beets	46974608	264	OWN	RAJAY024
860.1500	Crop field study, sugar beets	49533303	264	OWN	M-518342-01-1
860.1500	Crop field study, wheat	46246218	264	OWN	200521

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Applicant's/Registrant's Name & Address: [illegible]	Product: [illegible]	

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Date: June 22, 2015		EPA Reg. No./File Symbol: 264-824	Page 19 of 28
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.SUPP	Tier II Summaries for Residue Chemistry - cotton	4953306	264	OWN	
Toxicology Data Requirements					
870.1100	Acute oral toxicity, rat – JAU	46246230	264	OWN	08996
870.1100	Acute oral toxicity, rat - SXX	46246231	264	OWN	109274
870.1100	Acute oral toxicity, rat – JAU asymmetric isomer	46246233	264	OWN	32125
870.1100	Acute oral toxicity, rat – JAU des-chloro	46246234	264	OWN	AT00329
870.1100	Acute oral toxicity, rat – JAU methyl	46246235	264	OWN	31997
870.1100	Acute oral toxicity, rat– JAU asymmetric disulfide	46246236	264	OWN	31498
870.1100	Acute oral toxicity, rat – JAU sulfonic acid K salt	46246237	264	OWN	30237
870.1100	Acute oral toxicity, rat – JAU alpha-hydroxy-desthio	46246238	264	OWN	30109
870.1100	Acute oral toxicity, rat – JAU alpha-acetoxy-desthio	46246239	264	OWN	30110
870.1100	Acute oral toxicity, rat – JAU benzylpropyldiol	46246240	264	OWN	29898
870.1100	Acute oral toxicity, rat – JAU triazolinone	46246241	264	OWN	30108
870.1100	Acute oral toxicity, mouse - SXX	46246242	264	OWN	109278
870.1200	Acute dermal toxicity, rat - SXX	46246243	264	OWN	109276
870.1200	Acute dermal toxicity, rat - JAU	46246244	264	OWN	108994
870.1300	Acute inhalation Toxicity, rat - JAU	46246246	264	OWN	109267
870.1300	Acute inhalation Toxicity, rat - SXX	46246247	264	OWN	109275

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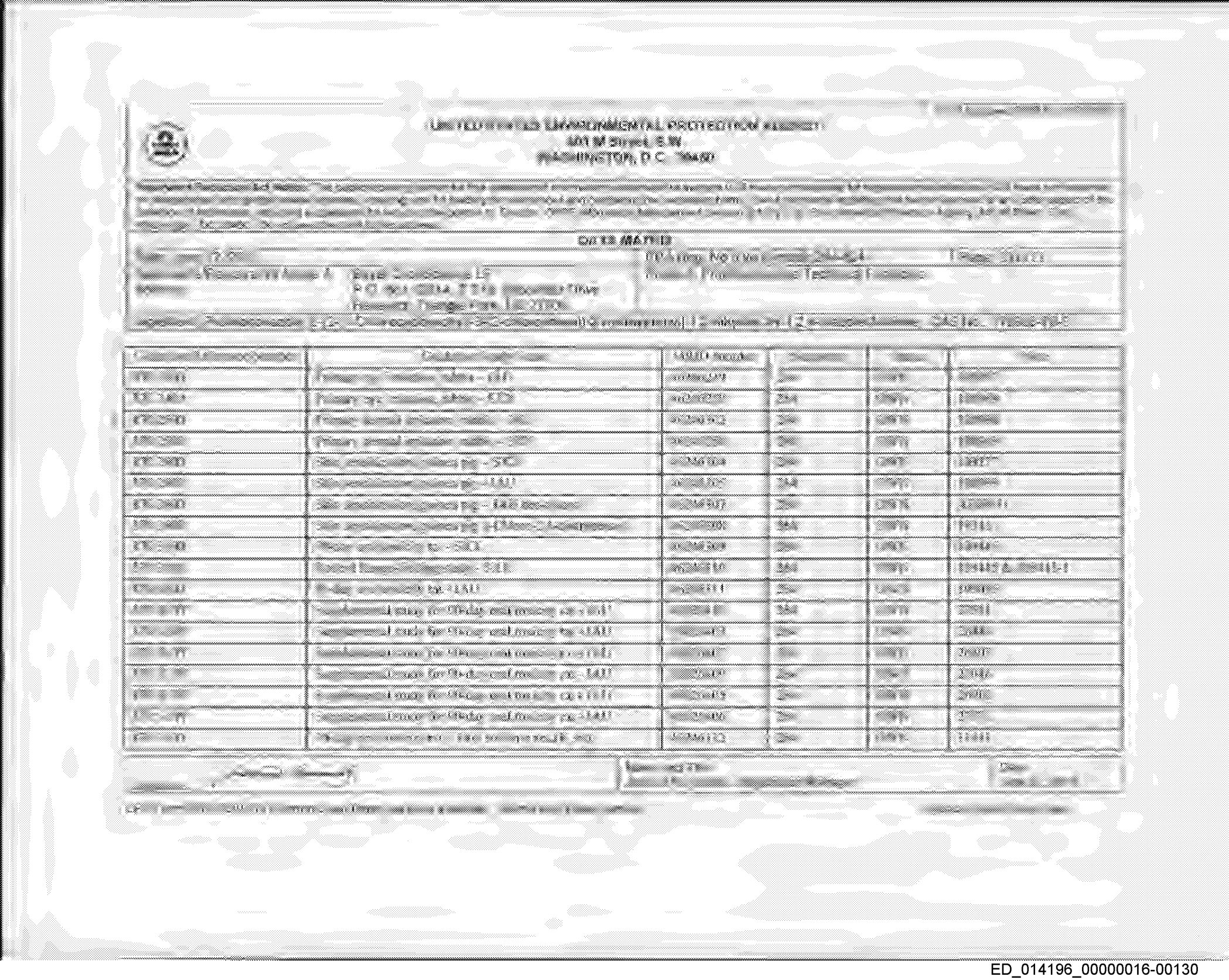

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Date: June 22, 2015	EPA Reg. No./File Symbol: 264-824	Page 21 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3150	90-day feeding study dog - JAU	46246313	264	OWN	109442
870.3150	90-day feeding study dog - SXX	46246314	264	OWN	29616
870.3200	21day dermal toxicity - JAU	46246315	264	OWN	30115
870.3700	Developmental toxicity rat - JAU	46246316	264	OWN	109074
870.3700	Developmental toxicity rat – JAU des-chloro	46246317	264	OWN	AT00172
870.3700	Developmental toxicity rat – JAU sulfonic acid K salt	46246318	264	OWN	R7936
870.3700	Developmental toxicity rat - SXX	46246319	264	OWN	109269
870.3700	Developmental toxicity rat - SXX	46246320	264	OWN	18661
870.3700	Developmental toxicity rat - SXX	46246321	264	OWN	108979
870.3700	Developmental toxicity rat - SXX	46246322	264	OWN	108979-1
870.3700	Developmental dermal toxicity rat - JAU	46246323	264	OWN	108993
870.3700	Developmental toxicity rat – JAU sulfonic acid K salt	46246324	264	OWN	R7997
870.3700	Developmental dermal toxicity rat - SXX	46246325	264	OWN	109280
870.3700	Developmental dermal toxicity rat - SXX	46246326	264	OWN	109280-1
870.3700	Supplemental pre-natal developmental toxicity rat	46923601	264	OWN	201037
870.3700	Developmental oral toxicity rabbit - SXX	46246327	264	OWN	109270
870.3700	Developmental toxicity rabbit - JAU	46246328	264	OWN	108657
870.3700	Developmental dermal toxicity rabbit - SXX	46246329	264	OWN	R5425

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Date: June 22, 2015		EPA Reg. No./File Symbol: 264-824	Page 23 of 28
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Gene mutation, Ames – JAU-asymmetric disulfide	46246348	264	OWN	31565
870.5100	Gene mutation, Ames – JAU-alpha-hydroxy-desthio	46246349	264	OWN	30086
870.5100	Gene mutation, Ames – JAU-triazolinone	46246350	264	OWN	30063
870.5100	Gene mutation, Ames – JAUalpha-acetoxy-desthio	46246401	264	OWN	30004
870.5100	Gene mutation, Ames – JAU sulfonic acid K salt	46246402	264	OWN	29969
870.5100	Gene mutation, Ames - JAUbenzylpropyldiol	46246403	264	OWN	29700
870.5300	Cell Gene mutation - JAU	46246404	264	OWN	109056
870.5300	Cell Gene mutation - SXX	46246405	264	OWN	109284
870.5375	Chromosome aberration test - JAU	46246406	264	OWN	109057
870.5375	Chromosome aberration test - SXX	46246407	264	OWN	108971
870.5375	Chromosome aberration test – JAU des-chloro	46246408	264	OWN	AT00321
870.5395	Micronucleus Test - JAU	46246409	264	OWN	109058
870.5395	Micronucleus Test - SXX	46246410	264	OWN	108974
870.5395	Micronucleus Test - JAU	46246411	264	OWN	T5072907
870.5550	Unscheduled DNA Synthesis - JAU	46246412	264	OWN	109059
870.5550	Unscheduled DNA Synthesis - JAU	46246413	264	OWN	109253
870.5550	Unscheduled DNA Synthesis - SXX	46246414	264	OWN	108975
870.5550	Inhibition of cytochrome - JAU	46246415	264	OWN	109060

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Jessica Fernandez	Jessica Fernandez, Registration Manager	June 22, 2015

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Date: June 22, 2015		EPA Reg. No./File Symbol: 264-824	Page 24 of 28
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6200	Subchronic neurotoxicity screen rat - JAU	46246416	264	OWN	109968
870.6200	Acute neurotoxicity screen rat - JAU	46246417	264	OWN	109250
870.6300	Developmental Neurotoxicity Screen rat - SXX	46246418	264	OWN	200958
870.6300	Developmental Neurotoxicity Screen rat – SXX – brain morphometric data	47293901	264	OWN	200958-1
870.7485	Metabolism rat - JAU	46246419	264	OWN	MR-437/01
870.7485	Metabolism rat - SXX	46246420	264	OWN	PF 3554
870.7485	Metabolism rat - JAU triazole & phenyl label	46246421	264	OWN	MR-251/01
870.7485	Metabolism rat – SXX pilot	46246422	264	OWN	MR-056/01
870.7600	Dermal penetration monkeys - JAU	46246423	264	OWN	200388
870.7600	Dermal penetration monkeys - SXX	46246424	264	OWN	200486
870.7600	Dermal penetration monkeys – SXX in SC 480	46246425	264	OWN	200487
870.7600	Dermal penetration monkeys – JAU 250 EC pilot	46246426	264	OWN	MR-545/97
870.7800	Immunotoxicity – Waiver Request	48020401	264	OWN	031010
870.None	Range-finding study in CD-1 mice - JAU	46246427	264	OWN	109063
870.None	Subacute oral, rat - JAU	46246428	264	OWN	109061
870.None	Subacute oral, rat – JAU	46246429	264	OWN	109062
870.None	Subacute oral, rat - SXX	46246430	264	OWN	109271

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Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxpropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.None	Subacute oral, dog - SXX	46246431	264	OWN	109272
870.None	Subacute inhalation, rat - SXX	46246432	264	OWN	109273
870.None	Subacute inhalation, rat - SXX	46246433	264	OWN	109283
870.None	Acute intraperitoneal - SXX	46246434	264	OWN	109279
870.None	Mechanistic subchronic dog - JAU	46246435	264	OWN	30260
870.None	Thyroid peroxidase-catalyzed reactions - JAU	46246436	264	OWN	25157
870.None	Liver foci test – SXX	46246437	264	OWN	20900
870.None	Plaque-forming cell assay in mice - JAU	46246438	264	OWN	32090
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020408	264	OWN	31085
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020402	264	OWN	AT00215
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020404	264	OWN	29004
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46195206	264	OWN	29019
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46195201	264	OWN	PH-30640
870.None	Plasma kinetics – SXX	46246439	264	OWN	MR-514/00
870.None	Analytical-LC method for dose determinations - JAU	46246440	264	OWN	108384
870.None	Assessment of ovarian findings in rodents - SXX	46246441	264	OWN	MO-02-000457
870.None	Validation of the Magnusoon-Kligman Maximization Test Method	46246442	264	OWN	24605

Signature	Name and Title	Date
Jessica Fernandez	Jessica Fernandez, Registration Manager	June 22, 2015

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DATA REVIEW

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DATA MATRIX

Exhibit 12

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DATA MATRIX

Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824 Page 1 of 2
Applicant's/Registrant's Name & Address: Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy Data					
§10.None	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 1 Wheat	46246005	261	(IWS)	BYER-AN005-1
§10.None	Prothioconazole Fusarium head blight deficiency response in wheat	46477705	261	(IWS)	BYER-AN005-W
§10.None	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 2 Barley	46246006	264	(IWS)	BYER-AN005-2
§10.None	Prothioconazole Fusarium head blight deficiency response in barley	46477706	264	(IWS)	BYER-AN005-B
§10.None	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 3 Canola	46246007	264	(IWS)	BYER-AN005-3
§10.None	Prothioconazole 480 SC Fungicide for Control of Diseases in Pulse Crops, Cereal Crops, Canola and Rapeseed Volume 4 Chickpea	46246008	264	(IWS)	BYER-AN005-4
Product Chemistry Data Requirements					
§830.1550	Identity of ingredients	46246002	261	(IWS)	BR 2281
§830.1550	Identity of ingredients	46246001	261	(IWS)	1501200050
§830.1550	Identity of ingredients	46477401	261	(IWS)	BR 3383

Signature:	Name and Title: Jessica Farnsworth, Registration Manager	Date: September 18, 2012

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DATA MATRIX

Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824 Page 2 of 3
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1600	Description of Materials	46246002	264	OWN	BR 2281
830.1600	Description of Materials	46246001	264	OWN	1401200950
830.1600	Description of Materials	48890202	264	OWN	M-436603-01-2
830.1600	Description of Materials	48890203	264	OWN	M-437333-01-3
830.1620	Description of Production Process	46246002	264	OWN	BR 2281
830.1620	Description of Production Process	46246001	264	OWN	1401200950
830.1620	Description of Production Process	46477401	264	OWN	BR 2383
830.1620	Description of Production Process	48890202	264	OWN	M-436603-01-2
830.1630	Description of Formulation Process	46246002	264	OWN	BR 2281
830.1630	Description of Formulation Process	46246001	264	OWN	1401200950
830.1670	Formulation of Impurities	46246002	264	OWN	BR 2281
830.1670	Formulation of Impurities	46246001	264	OWN	1401200950
830.1670	Formulation of Impurities	48890204	264	OWN	M-436598-01-2
830.1700	Preliminary Analysis	46246002	264	OWN	BR 2281
830.1700	Preliminary Analysis	46246001	264	OWN	1401200950
830.1700	Preliminary Analysis	46477401	264	OWN	BR 2383
830.1700	Preliminary Analysis	48890201	264	OWN	M-436600-01-2
830.1700	Preliminary Analysis	48890205	264	OWN	M-437333-01-2

Signature:	Name and Title: Jessica Fernandez, Registration Manager	Date: September 18, 2012

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DATA MATRIX

Date: September 18, 2012	EPA Reg. No./File Symbol: 264-624	Page 1 of 2
Applicant's/Registrant's Name & Address: Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1700	Preliminary Analysis	[illegible]	Bay	GDCN	MRID [illegible]
830.1750	Certified limits	46246002	264	GDWN	BR 2281
830.1750	Certified Limits	46246001	264	GDWN	1401200950
830.1800	Analytical Method	46246002	264	GDWN	BR 2281
830.1800	Analytical Method	46246001	264	GDWN	1401200950
830.1800	Analytical Method	[illegible]	264	GDWN	MRID [illegible]
830.1800	Analytical Method	[illegible]	264	GDWN	MRID [illegible]
830.1800	Analytical Method	[illegible]	264	GDWN	MRID [illegible]
830.1800	Analytical Method	[illegible]	264	GDWN	MRID [illegible]
830.1800	Analytical Method	[illegible]	264	GDWN	MRID [illegible]
830.1900	Submittal of samples	46246002	264	GDWN	BR 2281
830.1900	Submittal of samples	46246001	264	GDWN	1401200950
830.6302	Appearance	46246002	264	GDWN	BR 2282
830.6302	Appearance	46246001	264	GDWN	1401200951
830.6303	Physical state	46246002	264	GDWN	BR 2282
830.6303	Physical state	46246001	264	GDWN	1401200950
830.6304	Odor	46246002	264	GDWN	BR 2282

Signature: [signature] | Name and Title: Jessica Fernandez, Registration Manager | Date: September 18, 2012

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DATA MATRIX

Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824 — Page 1 of 21
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6304	Odor	46346001	264	OWN	1401200950
830.6313	Stability	46346003	264	OWN	BR 2282
830.6313	Stability	46346001	264	OWN	1401200950
830.6314	Oxidizing or reduction potential	46346003	264	OWN	BR 2282
830.6314	Oxidizing or reduction potential	46346001	264	OWN	1401200950
830.6315	Flammability	46346003	264	OWN	BR 2282
830.6315	Flammability	46346001	264	OWN	1401200950
830.6316	Explodability	46346003	264	OWN	BR 2282
830.6316	Explodability	46346001	264	OWN	1401200950
830.6317	Storage stability	46346003	264	OWN	BR 2282
830.6319	Miscibility	46346003	264	OWN	BR 2282
830.6319	Miscibility	46346001	264	OWN	1401200950
830.6320	Corrosion characteristics	46346003	264	OWN	BR 2282
830.6320	Corrosion characteristics	46346001	264	OWN	1401200950
830.6321	Dielectric breakdown	46346003	264	OWN	BR 2282
830.6321	Dielectric breakdown	46346001	264	OWN	1401200950
830.7000	pH	46346003	264	OWN	BR 2282
830.7000	pH	46346001	264	OWN	1401200950

Signature	Name and Title: Jessica Fernandez, Registration Manager	Date: September 18, 2012

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DATA MATRIX

Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824	Page 2 of 38
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7050	UV/Visible absorption	46246001	264	DWN	BR 2282
830.7050	UV/Visible absorption	46246001	264	DWN	1401200950
830.7100	Viscosity	46246003	264	DWN	BR 2282
830.7100	Viscosity	46246001	264	DWN	1401200950
830.7200	Melting point	46246003	264	DWN	BR 2282
830.7200	Melting point	46246001	264	DWN	1401200950
830.7220	Boiling point	46246003	264	DWN	BR 2282
830.7220	Boiling point	46246001	264	DWN	1401200950
830.7300	Density, bulk density or specific gravity	46246003	264	DWN	BR 2282
830.7300	Density, bulk density or specific gravity	46246001	264	DWN	1401200950
830.7370	Dissociation constant	46246003	264	DWN	BR 2282
830.7370	Dissociation constant	46246001	264	DWN	1401200950
830.7520	Particle size, fiber length, and diameter distribution	46246003	264	DWN	BR 2282
830.7520	Particle size, fiber length, and diameter distribution	46246001	264	DWN	1401200950
830.7550	Octanol/water partition coefficient	46246003	264	DWN	BR 2282
830.7550	Octanol/water partition coefficient	46246001	264	DWN	1401200950
830.7550	Octanol/water partition coefficient (KOC)	46220401	264	DWN	40405907
830.7560	Octanol/water partition coefficient	46246002	264	DWN	BR 2282

Signature: [signature] | Name and Title: Jessica Fernandez, Registration Manager | Date: September 18, 2012

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DATA MATRIX

Date: September 16, 2012	EPA Reg. No./File Symbol: 264-824	Page: 6 of 7
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560	Octanol/water partition coefficient	46246001	264	OWN	1401200950
830.7570	Octanol/water partition coefficient	46246003	264	OWN	BR 2282
830.7570	Octanol/water partition coefficient	46246001	264	OWN	1401200950
830.7840	Solubility	46246003	264	OWN	BR 2282
830.7840	Solubility	46246001	264	OWN	1401200950
830.7860	Solubility	46246003	264	OWN	BR 2282
830.7860	Solubility	46246001	264	OWN	1401200950
830.7950	Vapor pressure	46246003	264	OWN	BR 2282
830.7950	Vapor pressure	46246001	264	OWN	1401200950
Environmental Fate Data Requirements					
835.1230	Soil adsorption/desorption - JAU	46246449	264	OWN	MR-473/00
835.1230	Soil adsorption/desorption - SXX	46246450	264	OWN	FM768
835.1230	Soil adsorption/desorption - JAU S-methyl	46246501	264	OWN	FM774
835.1230	Soil adsorption/desorption - JAU-triazolinone	46246502	264	OWN	MR-265/01
835.1240	Leaching behavior - JAU	46246503	264	OWN	MR-098/00
835.1240	Aged column leaching - JAU	46246504	264	OWN	MR-364/00
835.1240	Parent column leaching - 280 EC	46246539	264	OWN	109139
835.2120	Hydrolysis - JAU phenyl	46246505	264	OWN	MR-623/98

Signature: [signature]	Name and Title: Jessica Fernandes, Registration Manager	Date: September 16, 2012

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DATA MATRIX

Date: September 16, 2010	EPA Reg. No./File Symbol: 264-824 Page [illegible]
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2120	Hydrolysis - SXX	46246506	264	OWN	PF 3882
835.2240	Photodegradation in water - JAU	46246507	264	OWN	MR-213/01
835.2240	Photodegradation Quantum Yield & half life - JAU	46246508	264	OWN	MR-101/01
835.2240	Photodegradation Quantum Yield & half life - SXX	46246509	264	OWN	PF 3852
835.2370	Photodegradation in air - SXX	46246542	264	OWN	MR-323/01
835.2370	Photodegradation in air JAU 6476	46246543	264	OWN	MR-093/99
835.2410	Soil photolysis - JAU	46246510	264	OWN	MR-242/00
835.2410	Photodegradation on soil	46339101	264	OWN	MR-243/00
835.4100	Aerobic soil metabolism - JAU	46246511	264	OWN	MR-104/01
835.4100	Aerobic soil metabolism - JAU	46246512	264	OWN	MR-549/00
835.4100	Aerobic soil metabolism - SXX	46246513	264	OWN	MR-527/00
835.4100	Aerobic soil metabolism - JAU S-methyl	46246514	264	OWN	MR-240/00
835.4100	Aerobic soil metabolism	46339102	264	OWN	MR-549/99
835.4300	Aerobic aquatic metabolism - JAU	46246515	264	OWN	MR-395/01
835.4400	Anaerobic aquatic metabolism - JAU	46246516	264	OWN	MR-275/01
835.6100	Field dissipation California	46246517	264	OWN	200051
835.6100	Field dissipation Georgia	46246518	264	OWN	110799
835.6100	Field dissipation New York	46246519	264	OWN	200053

Signature: [signature]	Name and Title: Jessica Fernandez, Registration Manager	Date: September 16, 2010

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DATA MATRIX

Date: September 18, 2015	EPA Reg. No./File Symbol: 264-824	Page: 6 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,3-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6100	Field dissipation Southeastern	46246530	264	GWN	200834
835.6100	Field dissipation Northern - EAU	46246531	264	GWN	200890
835.6100	Storage stability, soil	46246525	264	GWN	MR-644/09
835.6100	Field Dissipation Europe	46246526	264	GWN	B-442153/98
835.6100	Storage stability, metabolite in soil	46246528	264	GWN	100305
835.6100	Storage stability, soil - EAU & metabolites	46246544	264	GWN	MR-681/02
835.6200	Aquatic field dissipation California	46246522	264	GWN	200860
835.6200	Aquatic field dissipation Arkansas	46246523	264	GWN	200867
835.6200	Aquatic field dissipation Arkansas	46246524	264	GWN	200878
835.None	DT50 for EAU and metabolites in water	46246527	264	GWN	200881
835.None	DT50 for triazole in water	46246528	264	GWN	200887
835.None	DT50 for EAU and metabolites in soil	46246529	264	GWN	200882
835.None	DT50 for triazole in soil	46246530	264	GWN	200401
835.None	Soil mineralization method - EAU & metabolites	46246531	264	GWN	200815
835.None	Soil and sediment method - triazole	46246532	264	GWN	200516
835.None	Water method triazole	46246533	264	GWN	200519
835.None	Soil Koc - EAU	46246534	264	GWN	200817
835.None	Water & sediment method - EAU & metabolites	46246535	264	GWN	200817

Signature:

Name and Title: Jennifer Fernandez, Registration Manager

Date: September 18, 2015

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Date: September 19, 2012 | EPA Reg. No./File Symbol: 264-824 |

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.None	Temperature referenced field half-lives – JAU & SXX	46246536	264	OWN	200731
835.None	Aquatic Environment and Drinking Water Exposure Assessment of JAU 6476 & Major Metabolites	46246537	264	OWN	200840
835.None	Degradation of JAU 6476 & its major metabolites in two sediment-water systems under aerobic conditions	46246540	264	OWN	200841
835.None	Aquatic Environmental and Drinking Water Assessment of Prothioconazole and Major Metabolites Resulting from Prothioconazole Use on Rice	48024603	264	OWN	MEJAY008
835.None	Aquatic Ecological & drinking water exposure assessment for JAU 6476 & its major metabolites resulting from JAU 6476 use on barley, canola, dry beans, peanuts & wheat	46246541	264	OWN	200842
835.None	Soil residues – JAU & metabolites	46246543	264	OWN	MR-64394
835.None	Calculation of half-life in soil	46246546	264	OWN	MR-383/01
835.None	Tier II summaries for environmental fate studies	46246547	264	OWN	201005
835.None	Environmental Fate and Ecotox Risk Assessment Nursery, Rice and Seed Treatment Uses	48526701	261	OWN	US0196
Ecological Effects Data Requirements					
850.1010	Invertebrates toxicity – 480 SC	46246009	264	OWN	HBF DM 212
850.1010	Invertebrates toxicity – JAU	46246010	264	OWN	200314
850.1010	Invertebrates toxicity – SXX	46246011	261	OWN	HBF/DM 95

Signature: [signature]

Name and Title: Jessica Fernandez, Registration Manager

Date: September 18, 2012

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Date: September 18, 2012 | EPA Reg. No./File Symbol: 264-824 | Page: 19 of 25

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1010	Invertebrate toxicity – S-Methyl	46246012	264	OWN	DOM 21055
850.1010	Invertebrate toxicity – SXX	46246013	264	OWN	200985
850.1025	Estuarine/marine tox. mollusc – JAU	46246014	264	OWN	110936
850.1025	Method validation marine studies – JAU	46246015	264	OWN	110957
850.1035	Estuarine/marine tox. shrimp – JAU	46246016	264	OWN	110963
850.1035	Estuarine/marine tox. shrimp – SXX	46246017	264	OWN	110979
850.1075	Fish toxicity trout – JAU	46246018	264	OWN	DOM 99076
850.1075	Fish toxicity trout – 480 SC	46246019	264	OWN	200193
850.1075	Fish toxicity trout – SXX	46246020	264	OWN	FF-298
850.1075	Fish toxicity trout – S-Methyl	46246021	264	OWN	DOM 21047
850.1075	Fish toxicity bluegill LC50 – JAU	46246022	264	OWN	DOM 99090
850.1075	Fish toxicity bluegill – 480 SC	46246023	264	OWN	200599
850.1075	Fish toxicity orfe – SXX	46246024	264	OWN	FO-1253
850.1075	Fish toxicity carp – JAU	46246025	264	OWN	DOM 20040
850.1075	Fish toxicity fathead minnow – SXX	46246026	264	OWN	200151
850.1075	Fish toxicity sheepshead minnow – JAU	46246027	264	OWN	200615
850.1300	Chronic toxicity daphnia	46246028	264	OWN	HDB/KOOM 67
850.1300	Chronic toxicity daphnia – SXX	46246029	264	OWN	DOM 21036

Signature: [signature]

Name and Title: Jessica Fernchak, Registration Manager

Date: September 18, 2012

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Date: September 18, 2012 | EPA Reg. No./File Symbol: 264-XXX | Page 11 of 35

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1350	Invertebrate life cycle, marine – SXX	46246030	264	OWN	200485
850.1400	Fish early life stage, freshwater – JAU	46246031	264	OWN	DOM 20028
850.1400	Fish early life stage, freshwater – SXX	46246032	264	OWN	[illegible]
850.1500	Fish life cycle, fathead minnow – SXX	46246033	264	OWN	200102
850.1730	Fish BCF – JAU	46246034	264	OWN	DOM 21003
850.1730	Fish BCF – SXX	46246035	264	OWN	DOM 20006
850.2100	Acute avian oral LD 50, quail – JAU	46246036	264	OWN	BAR/LD 028
850.2100	Acute avian oral LD 50, quail – SXX	46246037	264	OWN	VB-009
850.2100	Acute avian oral LD 50, Canary (passerine)	48034801	264	OWN	EBLM 065
850.2200	Avian dietary LC 50 Quail	46246038	264	OWN	BAR/LC 005
850.2200	Avian reproduction, quail – SXX	46246039	264	OWN	BAR/LC 011
850.2200	Avian reproduction, duck – JAU	46246040	264	OWN	BAR/LC 010
850.2100	Avian analytical method – SXX	46246041	264	OWN	110161
850.2300	Avian reproduction, quail – JAU	46246042	264	OWN	259843
850.2300	Avian reproduction, quail – SXX	46246043	264	OWN	BAR/REP006
850.2300	Avian reproduction, duck – JAU	46246044	264	OWN	259919
850.2300	Avian reproduction, duck – SXX	46246045	264	OWN	110617
850.3020	Acute toxicity honey bee – 480 SC	46246046	264	OWN	[illegible]

Signature: [signature] | Name and Title: Jessica Fernandez, Registration Manager | Date: September 18, 2012

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Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824	Page [illegible]
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.3020	Parasitoid *Aphidius rhopalosiphi* – 480 SC	46246047	264	OWN	18512002
850.3020	Acute toxicity honey bee – JAU	46246048	264	OWN	IBA 63051
850.4000	Non-target plant testing – 480 SC	46246049	264	OWN	200951
850.4100	Seedling emergence, Tier I – 480 SC	46246049	264	OWN	200951
850.4150	Vegetative vigor, Tier I – 480 SC	46246049	264	OWN	200951
850.4000	Non-target plant testing – 480 SC	46246050	264	OWN	200951
850.4225	Seedling emergence, Tier 2 – 480 SC	46246050	264	OWN	200951
850.4250	Vegetative vigor, Tier 2 – 480 SC	46246050	264	OWN	200952
850.4400	Aquatic plant growth, duckweed – JAU	46246101	264	OWN	200488
850.4400	Aquatic Plant Growth, duckweed – 480 SC	46246102	264	OWN	200872
850.4400	Aquatic Plant Growth, bluegreen algae – JAU	46246103	264	OWN	200497
850.4400	Aquatic plant growth – SXX	46246104	264	OWN	200489
850.5400	Algae toxicity, *Selenastrum* (green algae) – JAU	46246105	264	OWN	DOM 99105
850.5400	Algae toxicity, *Pseudokirchneriella* (green algae) – 480 SC	46246106	264	OWN	2004[illegible]
850.5400	Algae toxicity, *Selenastrum* (green algae) – S-Methyl	46246107	264	OWN	DOM 21026
850.5400	Algae toxicity, *Scenedesmus* (green algae) – SXX	46246108	264	OWN	HBF AL58
850.5400	Algae toxicity, *Navicula* – JAU	46246109	264	OWN	200352
850.5400	Algae toxicity, *Skeletonema* – JAU	46246110	264	OWN	200434

Signature: [signature]	Name and Title: Jessica Fernandez, Registration Manager	Date: September 19, 2012

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Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824	Page 13 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No. 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.None	Predaceous mite - JAU	46246111	264	OWN	000111
850.None	Soil microbial mineralization – JAU	46246112	264	OWN	AJO/203199
850.None	Soil glucose stimulated respiration – JAU	46246113	264	OWN	AJO/203099
850.None	Soil microbial mineralization – SXX	46246114	264	OWN	AJO/289400
850.None	Soil microbial mineralization – SXX	46246115	264	OWN	AJO/219101
850.None	Soil microbial mineralization – S-Methyl	46246116	264	OWN	AJO/203599
850.None	Soil glucose stimulated respiration – S-Methyl	46246117	264	OWN	AJO/203299
850.None	Reproduction Toxicity, *Folsomia* – JAU	46246118	264	OWN	1022.028.641
850.None	Reproduction Toxicity, *Folsomia* – SXX	46246119	264	OWN	PICB
850.None	Reproduction Toxicity, *Folsomia* – SXX	46246120	264	OWN	1022.020.641
850.None	Reproduction Toxicity, *Folsomia* – S-Methyl	46246121	264	OWN	P35CB
850.None	Acute toxicity earthworm – JAU	46246122	264	OWN	MPE/Rg 320/00
850.None	Acute toxicity earthworm – EC 250	46246123	264	OWN	MPE/Rg 331/00
850.None	Acute toxicity earthworm – 480 SC	46246124	264	OWN	LKC/Rg-A 16/01
850.None	Acute toxicity earthworm – SXX	46246125	264	OWN	MPE/Rg 338/00
850.None	Chronic toxicity earthworm – S-Methyl	46246126	264	OWN	HBF/Rg 520
850.None	Chronic toxicity earthworm – EC 250	46246127	264	OWN	MPE/Rg 523/00
850.None	Chronic toxicity earthworm – SXX	46246128	264	OWN	MPE/Rg 192/00

Signature	Name and Title	Date
[signature]	Jessica Fernandes, Regulatory Manager	September 18, 2012

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Date: September 14, 2012	EPA Reg. No./File Symbol: 264-824	Page 18 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione. CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850 None	Acute toxicity earthworm – (Aleny)	46246129	264	OWN	HBF/Rg-17
850 None	Earthworm fauna in grassland area – EC 250	46246130	264	OWN	LK/179-F 58
850 None	Development & emergence *Chironomus riparius* – JAU	46246131	264	OWN	HDB/Ch 42
850 None	Development & emergence *Chironomus riparius* – SXX	46246132	264	OWN	HDB/Ch 43
850 None	Chironomus sediment full life-cycle study, SXX, OECD Guideline 218	4762590	264	OWN	EBTAY008
850 None	Wildlife residue wheat – 480 SC	46246133	264	OWN	111012
850 None	Wildlife residue oat – 480 SC	46246134	264	OWN	200832
850 None	Wildlife residue peanut – 480 SC	46246135	264	OWN	200833
850 None	Earthworm fauna in grassland area – EC 250	46246136	264	OWN	MO-02-01440
850 None	Effects on predatory mite *Typhlodromus pyri* – 480 SC	46246137	264	OWN	18551602
850 None	Environmental Risk Assessment – JAU	46246138	264	OWN	201080
850 None	Tier II Summaries for Ecotoxicology Studies – JAU	46246140	264	OWN	201082
850 None	Ecotox Risk Assessment for rice	48024802	264	OWN	US0017
850 None	Environmental Fate and Ecotox Risk Assessment Nursery, Rice and Seed Treatment Uses	48226701	264	OWN	US0196
Residue Chemistry Data Requirements					
860.1300	Nature of residue, wheat – JAU	46246141	264	OWN	110880
860.1300	Nature of residue, wheat, seed treatment – JAU	46246142	264	OWN	110881

Signature: [signature]	Name and Title: Jessica Fernandez, Registration Manager	Date: September 18, 2012

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Date: September 18, 2012 | EPA Reg. No./File Symbol: 264-824 | Page 15 of 26

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300	Nature of residue, wheat - triazole label - JAU	46246142	264	OWX	200737
860.1300	Nature of residue, wheat - SXX	46246143	264	OWX	MR-0F-2986
860.1300	Nature of residue, peanuts - phenyl label - JAU	46246145	264	OWX	MR-199/01
860.1300	Nature of residue, peanuts - triazole label - JAU	46246146	264	OWX	MR-194/02
860.1300	Nature of residue, sugar beet - triazole label - JAU	46246147	264	OWX	200467
860.1300	Nature of residue, sugar beet - phenyl label - JAU	46246148	264	OWX	200466
860.1300	Nature of residue, goat - triazole label - JAU	46246149	264	OWX	MR-448/02
860.1300	Nature of residue, goat - phenyl label - JAU	46246150	264	OWX	MR-092/01
860.1300	Nature of residue, goat - phenyl label desthio - SXX	46246201	264	OWX	MR-091/01
860.1300	Nature of residue, poultry - phenyl label - JAU	46246202	264	OWX	MR-380/01
860.1300	Nature of residue, poultry - triazole label - JAU	46246203	264	OWX	MEF-003/03
860.1300	TRR in alfalfa - seed treatment	46023901	264	OWX	MEDUP111
860.1300	TRR in potato - seed treatment	46023902	264	OWX	MEELP001
860.1340	Animal method - JAU & metabolites - JAU & metab	46246204	264	OWX	200537
860.1340	Animal method - JAU metabolite	46777704	264	OWX	MR-537/00
860.1340	Animal method - LC/MS/MS	47953301	264	OWX	TA-010-A10/07
860.1340	Animal method extraction efficiency - JAU & metab	46246205	264	OWX	MEF-020/04
860.1340	Crop residue method validation - JAU & metabolites	46246206	264	OWX	200098

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Date: September 18, 2012	EPA Reg. No./File Symbol: 264-[illegible]	Page 16 of 18
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione. CAS No. 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Animal method ILV	46246207	264	OWN	RAJAY004
860.1340	Crop method extraction efficiency	46246208	264	OWN	RAJAY011
860.1340	Crop residue method ILV	46246209	264	OWN	RAJAY020
860.1340	Crop method HPLC-MS/MS cereals JAU & SXX	46477702	264	OWN	MR-401/99
860.1340	Crop method HPLC-MS/MS cereals JAU & SXX (method modification 00[illegible]M001)	46477703	264	OWN	MR-[illegible]
860.1340	Crop method LC-MS/MS	47948901	264	OWN	JA-001-P08-02
860.1360	Method multiresidue	46246210	264	OWN	200480
860.1380	Storage stability in crop matrices (6-month data)	46246211	264	OWN	200K14
860.1380	Storage stability in crop deficiency study	46477901	264	OWN	201262
860.1380	Storage Stability in crops	47304201	264	OWN	RAJAY016
860.1380	Storage Stability wildlife residue crops JAU & SXX	46246139	264	OWN	MR-354/01
860.1380	45-day fat storage stability data	47187801	264	OWN	RAJAY040
860.1380	Storage stability triazole	47606601	US Triazole Task Force	Member	RAJAY006
860.1480	Feeding study, cattle—JAU	46246213	264	OWN	200715
860.1480	Feeding study, cattle—SXX	46246214	264	OWN	MR-535/00
860.1480	Feeding study, poultry—JAU	47982801	264	OWN	RAJAL001
860.1500	Crop field study, barley	46246229	264	OWN	200[illegible]

Signature: [signature]	Name and Title: Jessica Fernandez, Registration Manager	Date: September 18, 2012

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DATA MATRIX

Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824	Page 17 of 38
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, >= 97% (1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Crop field study, blueberry	48613501	Bay	OWN	M-420533-01-1
860.1500	Crop field study, canola	48246215	Bay	OWN	280484
860.1500	Crop field study, corn	47531901	Bay	OWN	RAJA9004
860.1500	Crop field study, corn HLV	48116901	Bay	OWN	RJSAP020-1
860.1500	Crop field study, corn seed treatment	48816202	Bay	OWN	RA-2567-07
860.1500	Crop field study, corn seed treatment	48516201	Bay	OWN	RA-423008
860.1500	Crop field study, corn seed treatment	48516204	Bay	OWN	RA-2568-07
860.1500	Crop field study, combined treatment	48516205	Bay	OWN	RA-385108
860.1500	Crop field study, cranberry	48803302	Bay	OWN	M-428531-01-1
860.1500	Crop field study, cucumber vegetables	48803305	Bay	OWN	M-428911-01-1
860.1500	Crop field study, peanuts	46246217	Bay	OWN	280598
860.1500	Crop field study, peanuts – bridging study (seed soil foliar)	47214701	Bay	OWN	RAJA9055
860.1500	Crop field study, pecs & nuts, dried	46246221	Bay	OWN	280931
860.1500	Potato – EU seed treatment	48034903	Bay	OWN	RJ-2569-05
860.1500	Potato – EU seed treatment	48034904	Bay	OWN	RJ-2614-05
860.1500	Crop field study, rice	46246216	Bay	OWN	280468
860.1500	Crop field study, soybean	46841901	Bay	OWN	RAJA9026
860.1500	Crop field study, sugar beet	46974008	Bay	OWN	RAJA9024

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Name and Title: Jessica Pemberton, Registration Manager

Date: September 18, 2012

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Date: September 18, 2012 | EPA Reg. No./File Symbol: 264-824 |

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione. CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Crop field study, wheat	46246218	264	OWN	200521
860.1500	Crop field study, wheat	46246219	264	OWN	200524
860.1500	Crop field study wheat – bridging study (seed, soil, foliar)	47577008	264	OWN	RAJAY039
860.1500	Crop field study wheat – translate from foliar to seed treatment uses on other crops	46024905	264	OWN	MEJAY007
860.1500	Crop field study corn and wheat – translate from foliar to seed treatment uses on other crops	48510201	264	OWN	MEJAY007-1
860.1520	Processing study, canola	46246224	264	OWN	200853
860.1520	Processing study, corn	47521903	264	OWN	RAJAB006
860.1520	Processing study, peanut	46246223	264	OWN	200518
860.1520	Processing study, rice	46246222	264	OWN	200493
860.1520	Processing study, soybean	46841005	264	OWN	RAJAY027
860.1520	Processing study, sugar beets	46734609	264	OWN	RAJAY025
860.1520	Processing & Crop field study, wheat	46246218	264	OWN	200521
860.1850	Confined rotational crop – phenyl label	46246225	264	OWN	110882
860.1850	Confined rotational crop – triazole label	46246226	264	OWN	200623
860.1900	Field rotational crop	46246227	264	OWN	200535
860.None	Dietary exposure assessment, acute & chronic	46246213	264	OWN	200996
860.None	Tier II Summaries for Residue Chemistry Studies	46246229	264	OWN	201084

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Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824	Page: 1 of 29
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Toxicology Data Requirements					
870.1100	Acute oral toxicity, rat - JAU	46246230	264	OWN	08986
870.1100	Acute oral toxicity, rat - SXX	46246231	264	OWN	109274
870.1100	Acute oral toxicity, rat - JAU asymmetric dimer	46246233	264	OWN	32125
870.1100	Acute oral toxicity, rat - JAU desthio	46246234	264	OWN	AT00329
870.1100	Acute oral toxicity, rat - JAU methyl	46246235	264	OWN	31997
870.1100	Acute oral toxicity, rat - JAU asymmetric disulfide	46246236	264	OWN	31498
870.1100	Acute oral toxicity, rat - JAU sulfonic acid K salt	46246237	264	OWN	30237
870.1100	Acute oral toxicity, rat - JAU alpha-hydroxy-desthio	46246238	264	OWN	30109
870.1100	Acute oral toxicity, rat - JAU alpha-acetoxy-desthio	46246239	264	OWN	30110
870.1100	Acute oral toxicity, rat - JAU benzylpropyldiol	46246240	264	OWN	29898
870.1100	Acute oral toxicity, rat - JAU triazolinone	46246241	264	OWN	30108
870.1100	Acute oral toxicity, mouse - SXX	46246242	264	OWN	109278
870.1200	Acute dermal toxicity, rat - SXX	46246243	264	OWN	109276
870.1200	Acute dermal toxicity, rat - JAU	46246244	264	OWN	108094
870.1300	Acute inhalation Toxicity, rat - JAU	46246246	264	OWN	109267
870.1300	Acute inhalation Toxicity, rat - SXX	46246247	264	OWN	109235
870.2400	Primary eye irritation, rabbit - JAU	46246249	264	OWN	108997

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Date: September 18, 2012 | EPA Reg. No./File Symbol: 264-824 | Page: 2 of 2[illegible]

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	[illegible]
870.2400	Primary eye irritation, rabbit – SXX	46246250	264	OWN	108969
870.2500	Primary dermal irritation, rabbit – JAU	46246302	264	OWN	108998
870.2500	Primary dermal irritation, rabbit – SXX	46246250	264	OWN	108969
870.2600	Skin sensitization, guinea pig – SXX	46246304	264	OWN	109277
870.2600	Skin sensitization, guinea pig – JAU	46246305	264	OWN	108999
870.2600	Skin sensitization, guinea pig – JAU (desthio)	46246307	264	OWN	AT00031
870.2600	Skin sensitization, guinea pig 1-Chloro-2,4-dinitrobenzol	46246308	264	OWN	19316
870.3100	90-day oral toxicity, rat – SXX	46246309	264	OWN	109446
870.3100	Rodent Range-finding study – SXX	46246310	264	OWN	109445 & 109445-1
870.3100	90-day oral toxicity rat – JAU	46246311	264	OWN	109097
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020410	264	OWN	27581
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020403	264	OWN	28844
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020407	264	OWN	26807
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020409	264	OWN	27086
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020405	264	OWN	26902
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020406	264	OWN	27[illegible]
870.3100	90-day oral toxicity rat – JAU sulfonic acid K salt	46246312	264	OWN	11441
870.3150	90-day feeding study dog – JAU	46246313	264	OWN	109862

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DATA MATRIX

Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824	Page: 21 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3150	90-day feeding study dog - SXX	46246314	264	OWN	29016
870.3200	21day dermal toxicity - JAU	46246315	264	OWN	30115
870.3700	Developmental toxicity rat - JAU	46246316	264	OWN	108078
870.3700	Developmental toxicity rat - JAU desthio	46246317	264	OWN	AT00172
870.3700	Developmental toxicity rat - JAU sulfonic acid K salt	46246318	264	OWN	87936
870.3700	Developmental toxicity rat - SXX	46246319	264	OWN	109269
870.3700	Developmental toxicity rat - SXX	46246320	264	OWN	18661
870.3700	Developmental toxicity rat - SXX	46246321	264	OWN	108979
870.3700	Developmental toxicity rat - SXX	46246322	264	OWN	108979-1
870.3700	Developmental dermal toxicity rat - JAU	46246323	264	OWN	108995
870.3700	Developmental toxicity rat - JAU sulfonic acid K salt	46246324	264	OWN	87907
870.3700	Developmental dermal toxicity rat - SXX	46246325	264	OWN	109280
870.3700	Developmental dermal toxicity rat - SXX	46246326	264	OWN	109280-1
870.3700	Supplemental prenatal developmental toxicity rat	46923800	264	OWN	200937
870.3700	Developmental oral toxicity rabbit - SXX	46246327	264	OWN	109270
870.3700	Developmental toxicity rabbit - JAU	46246328	264	OWN	108657
870.3700	Developmental dermal toxicity rabbit - SXX	46246329	264	OWN	85428
870.3700	Developmental toxicity rabbit - JAU	46246330	264	OWN	87003

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DATA MATRIX

Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824 Page 22 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3800	Reproduction/fertility rat - JAU	46246331	264	OWN	109079
870.3800	Reproduction/fertility rat - SXX	46246332	264	OWN	103274
870.3800	Reproduction/fertility rat - SXX	46246333	264	OWN	109835
870.3800	Reproduction/fertility rat - JAU	46246334	264	OWN	110800
870.4100	Rat chronic - JAU	46246335	264	OWN	30536
870.4100	Dog chronic - JAU	46246336	264	OWN	110921
870.4100	Dog chronic - SXX	46246337	264	OWN	31148
870.4200	Carcinogenicity rat - JAU	46246338	264	OWN	31512
870.4200	Carcinogenicity mouse - JAU	46246339	264	OWN	31510
870.4200	Carcinogenicity mouse - SXX	46246340	264	OWN	30845
870.4200	Carcinogenicity mouse - SXX	46246341	264	OWN	30845-1
870.4300	Chronic toxicity/carcinogenicity rat - SXX	46246342	264	OWN	109447
870.5100	Gene mutation, Ames - JAU	46246343	264	OWN	109055
870.5100	Gene mutation, Ames - SXX	46246344	264	OWN	108970
870.5100	Gene mutation, Ames - JAU-desthio	46246345	264	OWN	M1100304
870.5100	Gene mutation, Ames - JAU-methyl	46246346	264	OWN	32267
870.5100	Gene mutation, Ames - JAU-asymmetric [illegible]	46246347	264	OWN	32103
870.5100	Gene mutation, Ames - JAU-asymmetric disulfide	46246348	264	OWN	31565

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Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824	Page 2 of 21
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Gene mutation, Ames - JAU-alpha-hydroxy-desthio	46246349	264	OWN	30086
870.5100	Gene mutation, Ames - JAU-triazolinone	46246350	264	OWN	30063
870.5100	Gene mutation, Ames - JAU-alpha-acetoxy-desthio	46246401	264	OWN	30094
870.5100	Gene mutation, Ames - JAU-sulfonic acid K-salt	46246402	264	OWN	29969
870.5100	Gene mutation, Ames - JAU-benzylpropyldiol	46246403	264	OWN	29780
870.5300	Cell Gene mutation - JAU	46246404	264	OWN	109056
870.5300	Cell Gene mutation - SXX	46246405	264	OWN	109284
870.5375	Chromosome aberration test - JAU	46246406	264	OWN	109057
870.5375	Chromosome aberration test - SXX	46246407	264	OWN	108971
870.5375	Chromosome aberration test - JAU desthio	46246408	264	OWN	AT00211
870.5395	Micronucleus Test - JAU	46246409	264	OWN	109058
870.5395	Micronucleus Test - SXX	46246410	264	OWN	108974
870.5395	Micronucleus Test - JAU	46246411	264	OWN	T5032907
870.5550	Unscheduled DNA Synthesis - JAU	46246412	264	OWN	109059
870.5550	Unscheduled DNA Synthesis - JAU	46246413	264	OWN	109251
870.5550	Unscheduled DNA Synthesis - SXX	46246414	264	OWN	108975
870.5550	Inhibition of cytochrome - JAU	46246415	264	OWN	109060
870.6200	Subchronic neurotoxicity screen rat - JAU	46246416	264	OWN	109068

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Date: September 18, 2012 | EPA Reg. No./File Symbol: 264-824 | Page: 24 of 28

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6200	Acute neurotoxicity screen rat - JAU	46246417	264	OWN	100250
870.6300	Developmental Neurotoxicity Screen rat - SXX	46246418	264	OWN	200958
870.6300	Developmental Neurotoxicity Screen rat - SXX - brain morphometric data	47293901	264	OWN	200958-1
870.7485	Metabolism rat - JAU	46246419	264	OWN	MR-417/01
870.7485	Metabolism rat - SXX	46246420	264	OWN	PF 3554
870.7485	Metabolism rat - JAU triazole & phenyl label	46246421	264	OWN	MR-251/01
870.7485	Metabolism rat - SXX pilot	46246422	264	OWN	MR-056/01
870.7600	Dermal penetration monkeys - JAU	46246423	264	OWN	200388
870.7600	Dermal penetration monkeys - SXX	46246424	264	OWN	200486
870.7600	Dermal penetration monkeys - SXX in SC 480	46246425	264	OWN	200487
870.7600	Dermal penetration monkeys - JAU 250 EC pilot	46246426	264	OWN	MR-515/97
870.7800	Immunotoxicity - Waiver Request	48023801	264	OWN	031010
870.None	Range-finding study in CD-1 mice - JAU	46246427	264	OWN	109063
870.None	Subacute oral, rat - JAU	46246428	264	OWN	109061
870.None	Subacute oral, rat - JAU	46246429	264	OWN	109062
870.None	Subacute oral, rat - SXX	46246430	264	OWN	109271
870.None	Subacute oral, dog - SXX	46246431	264	OWN	109272

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.None	Subacute inhalation, rat - SXX	46246432	264	OWN	109273
870.None	Subacute inhalation, rat - SXX	46246433	264	OWN	109283
870.None	Acute intraperitoneal - SXX	46246434	264	OWN	109279
870.None	Mechanistic subchronic dog - JAU	46246435	264	OWN	30860
870.None	Thyroid peroxidase-catalyzed reactions - JAU	46246436	264	OWN	25157
870.None	Liver foci test - SXX	46246437	264	OWN	20900
870.None	Plaque-forming cell assay in mice - JAU	46246438	264	OWN	22090
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020408	264	OWN	31023
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020402	264	OWN	AT00215
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020404	264	OWN	29004
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46129206	264	OWN	29019
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46195201	264	OWN	PH-40640
870.None	Plasma kinetics - SXX	46246439	264	OWN	MR-51400
870.None	Analytical-LC method for dose determinations - JAU	46246440	264	OWN	108184
870.None	Assessment of ovarian findings in rodents - SXX	46246441	264	OWN	MO-02-000457
870.None	Validation of the Magnusson-Kligman Maximization Test Method	46246442	264	OWN	24869
870.None	Validation of the Magnusson-Kligman Maximization Test Method	46246443	264	OWN	AT00083

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Date: September 18, 2012		EPA Reg. No./File Symbol: 264-824	Page 30 of 31
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No. 178928-70-6			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.None	Analytical-LC method in rodent rations - SXX	46246844	264	OWN	101258
870.None	Tier II Summaries for Toxicology Studies	46246845	264	OWN	201031
Occupational & Residential Exposure					
875.2100	Foliar dislodgeable residue	46079102	264	OWN	Preliminary RAJAY028
875.2100	Foliar dislodgeable residue	47060201	264	OWN	RAJAY028
875.2100	Foliar dislodgeable residue	47623601	264	OWN	RAJAY028-1
875.Group A and B	Occupational Exposure and Safety Assessment for Prothioconazole	46246846	264	OWN	200951
875.Group A and B	Assessment of the Non-Dietary Exposure From the Addition of Cucurbits, Bushberries, and Low Growing Berries (except strawberries)	48003304	264	OWN	
875.Group A and B	Assessment of Non-Dietary Exposure on sweet, pop, and field corn	47521904	264	OWN	G201922
875.None	Determination of Exposure to JAU 6476 & JAU 6476-desthio (SXX0665) During Mixing/Loading & Application of JAU 6476 in Cereals	46246847	264	OWN	MR-036/02
875.None	Determination of Exposure to JAU 6476 & JAU 6476-desthio (SXX0665) During Mixing/Loading & Application of JAU 6476 in Cereals - Raw Data	47337601	264	OWN	MR-036/02-1
875.None	Tier II Summaries for Occupational and Residential Exposure	46246848	264	OWN	201086

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Date: September 18, 2012	EPA Reg. No./File Symbol: 264-824	Page: 21 of 28
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione. CAS No.: 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
1,2,4-Triazole and Derivatives		Cite-all	US Triazole Task Force	Member	
Spray Drift Data Requirements		Cite-all	Spray Drift Task Force	Member	
Reentry Data Requirements					
875 Group B	Residential exposure	Cite-all	Outdoor Residential Exposure Task Force	Member	
875 Group B	Reentry exposure	Cite-all	Agricultural Reentry Task Force	Member	
875 Group A	Handlers exposure data	Cite-all	Agricultural Handlers Exposure Task Force	Member	
Miscellaneous					
None	Tier III Summaries: Prothioconazole	46246548	264	OWN	
None	Proposal to Revise Application Pattern for Soybean	48786801	264	OWN	

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DATA MATRIX

Date: September 18, 2012		EPA Reg. No./File Symbol: 264-824	Page 38 of 38
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione, CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
None.	Public Interest Document	467(6301	264	OWS	BID - BAY05BN13

Signature:	Name and Title: Jessica Fernandez, Registration Manager	Date: September 18, 2012

Exhibit 13

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Date: May 18, 2012 | EPA Reg. No./File Symbol: 264-824 | Page [illegible] of 23

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione. CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy Data:					
810.None	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 1-Wheat	46246005	264	OWN	BYFCAN005-1
810.None	Prothioconazole Fusarium head blight deficiency response in wheat	46477005	264	OWN	BYFCAN005-W
810.None	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 2-Barley	46246006	264	OWN	BYFCAN005-2
810.None	Prothioconazole Fusarium head blight deficiency response in barley	46477006	264	OWN	BYFCAN005-B
810.None	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 3-Canola	46246007	264	OWN	BYFCAN005-3
810.None	Prothioconazole 480 SC Fungicide for Control of Diseases in Pulse Crops, Cereal Crops, Canola and Rapeseed Volume 4-Chickpea	46246008	264	OWN	BYFCAN005-4
Product Chemistry Data Requirements:					
830.1550	Identity of ingredients	46246002	264	OWN	BR 2281
830.1550	Identity of ingredients	46246001	264	OWN	M6120059
830.1550	Identity of ingredients	46477401	264	OWN	BR 2383

Signature: [signature]

Name and Title: Jessica Fernandez, Registration Manager

Date: May 18, 2012

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DATA MATRIX

Date: May 18, 2012	EPA Reg. No./File Symbol: 264-824	Page 1 of 2
Applicant/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1600	Description of Materials	46246802	264	UNK	BR 2281
830.1600	Description of Materials	46246800	264	UNK	14012009D
830.1620	Description of Production Process	46246802	264	UNK	BR 2281
830.1620	Description of Production Process	46246801	264	UNK	14012009D
830.1620	Description of Production Process	46477401	264	UNK	BR 2383
830.1650	Description of Formulation Process	46246803	264	UNK	BR 2281
830.1650	Description of Formulation Process	46246801	264	UNK	14012009D
830.1670	Formulation of Impurities	46246802	264	UNK	BR 2281
830.1670	Formulation of Impurities	46246801	264	UNK	14012009D
830.1700	Preliminary Analysis	46246802	264	UNK	BR 2281
830.1700	Preliminary Analysis	46246801	264	UNK	14012009D
830.1700	Preliminary Analysis	46477401	264	UNK	BR 2383
830.1750	Certified limits	46246802	264	UNK	BR 2281
830.1750	Certified Limits	46246801	264	UNK	14012009D
830.1800	Analytical Method	46246802	264	UNK	BR 2281
830.1800	Analytical Method	46246801	264	UNK	14012009D
830.1900	Submittal of samples	46246802	264	UNK	BR 2281
830.1900	Submittal of samples	46246801	264	UNK	14012009D

Signature:	Name and Title: Jessica Fernandez, Regulatory Manager	Date: May 18, 2012

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DATA MATRIX

Date: May 16, 2012	EPA Reg. No./File Symbol: 264-824	Page: 2 of 3
Applicant's/Registrant's Name & Address: Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Appearance	46246003	264	OWN	BR 3282
830.6302	Appearance	46246001	264	OWN	140120095D
830.6303	Physical state	46246003	264	OWN	BR 3282
830.6303	Physical state	46246001	264	OWN	140120095D
830.6304	Odor	46246003	264	OWN	BR 3282
830.6304	Odor	46246001	264	OWN	140120095D
830.6313	Stability	46246003	264	OWN	BR 3282
830.6313	Stability	46246001	264	OWN	140120095D
830.6314	Oxidizing or reduction potential	46246003	264	OWN	BR 3282
830.6314	Oxidizing or reduction potential	46246001	264	OWN	140120095D
830.6315	Flammability	46246003	264	OWN	BR 3282
830.6315	Flammability	46246001	264	OWN	140120095D
830.6316	Explosibility	46246003	264	OWN	BR 3282
830.6316	Explosibility	46246001	264	OWN	140120095D
830.6317	Storage stability	46246003	264	OWN	BR 3282
830.6319	Miscibility	46246003	264	OWN	BR 3282
830.6319	Miscibility	46246001	264	OWN	140120095D
830.6320	Corrosion characteristics	46246003	264	OWN	BR 3282

Signature: [signature] | Name and Title: Jessica Fernandez, Registration Manager | Date: May 16, 2012

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Date: May 15, 2012 | EPA Reg. No./File Symbol: 264-824 |

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6320	Corrosion characteristics	46246001	264	OWN	1401200950
830.6321	Dielectric breakdown	46246003	264	OWN	BR 2282
830.6321	Dielectric breakdown	46246001	264	OWN	1401200950
830.7000	pH	46246003	264	OWN	BR 2282
830.7000	pH	46246001	264	OWN	1401200950
830.7050	UV/Visible absorption	46246003	264	OWN	BR 2282
830.7050	UV/Visible absorption	46246001	264	OWN	1401200950
830.7100	Viscosity	46246003	264	OWN	BR 2282
830.7100	Viscosity	46246001	264	OWN	1401200950
830.7200	Melting point	46246003	264	OWN	BR 2282
830.7200	Melting point	46246001	264	OWN	1401200950
830.7220	Boiling point	46246003	264	OWN	BR 2282
830.7220	Boiling point	46246001	264	OWN	1401200950
830.7300	Density, bulk density, or specific gravity	46246003	264	OWN	BR 2282
830.7300	Density, bulk density, or specific gravity	46246001	264	OWN	1401200950
830.7370	Dissociation constant	46246003	264	OWN	BR 2282
830.7370	Dissociation constant	46246001	264	OWN	1401200950
830.7520	Particle size, fiber length, and diameter distribution	46246003	264	OWN	BR 2282

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Name and Title: Jessica Fernandez, Registration Manager

Date: May 15, 2012

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DATA MATRIX

Date: May 18, 2012	EPA Reg. No./File Symbol: 264-824 Page 1 of 21
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide
Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6	

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7520	Particle size, fiber length, and diameter distribution	46246001	264	OWN	1401200950
830.7550	Octanol/water partition coefficient	46270403	264	OWN	BR 2282
830.7550	Octanol/water partition coefficient	46246001	264	OWN	1401200950
830.7550	Octanol/water partition coefficient - SCX	46270401	264	OWN	[illegible]
830.7560	Octanol/water partition coefficient	46246003	264	OWN	BR 2282
830.7560	Octanol/water partition coefficient	46246001	264	OWN	1401200950
830.7570	Octanol/water partition coefficient	46246003	264	OWN	BR 2282
830.7570	Octanol/water partition coefficient	46246001	264	OWN	1401200950
830.7840	Solubility	46246003	264	OWN	BR 2282
830.7840	Solubility	46246001	264	OWN	1401200950
830.7860	Solubility	46246003	264	OWN	BR 2282
830.7860	Solubility	46246001	264	OWN	1401200950
830.7950	Vapor pressure	46246003	264	OWN	BR 2282
830.7950	Vapor pressure	46246001	264	OWN	1401200950
Environmental Fate Data Requirements					
835.1230	Soil adsorption/desorption - [illegible]	46246449	264	OWN	MR-472/00
835.1230	Soil adsorption/desorption - [illegible]	46246450	264	OWN	PM758
835.1230	Soil adsorption/desorption - [illegible] S-methyl	46246501	264	OWN	PM773

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DATA MATRIX

Date: May 18, 2015	EPA Reg. No./File Symbol: 264-[illegible]	Page [illegible] of [illegible]
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.1230	Soil adsorption/desorption – JAU [illegible]	46246502	264	OWN	MR-263/01
835.1240	Leaching [illegible] – JAU	46246503	264	OWN	MR-[illegible]
835.1240	Aged column leaching - JAU	46246504	264	OWN	MR-364/00
835.1240	Parent column leaching – 250 EC	46246539	264	OWN	109179
835.2120	Hydrolysis – JAU phenyl	46246505	264	OWN	MR-[illegible]
835.2120	Hydrolysis – SXX	46246506	264	OWN	PF 3862
835.2240	Photodegradation in water - JAU	46246507	264	OWN	MR-215/01
835.2240	Photodegradation Quantum Yield & half life - JAU	46246508	264	OWN	MR-101/01
835.2240	Photodegradation Quantum Yield & half life - SXX	46246509	264	OWN	PF 3852
835.2370	Photodegradation in air: SXX	46246542	264	OWN	MR-323/00
835.2370	Photodegradation in air: JAU 6476	46246543	264	OWN	MR-093/99
835.2410	Soil photolysis - JAU	46246510	264	OWN	MR-232/00
835.2410	Photodegradation on soil	46359101	264	OWN	MR-242/00
835.4100	Aerobic soil metabolism - JAU	46246511	264	OWN	MR-104/01
835.4100	Aerobic soil metabolism - JAU	46246512	264	OWN	MR-549/00
835.4100	Aerobic soil metabolism - SXX	46246513	264	OWN	MR-527/00
835.4100	Aerobic soil metabolism – JAU S-methyl	46246514	264	OWN	MR-540/00
835.4100	Aerobic soil metabolism	46359102	264	OWN	MR-[illegible]

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Date: May 18, 2012	EPA Reg. No./File Symbol: 264-824 Page: 1 of 3
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.4300	Aerobic aquatic metabolism - JAU	46246515	264	OWN	MR-395/01
835.4400	Anaerobic aquatic metabolism - JAU	46246516	264	OWN	MR-225/01
835.6100	Field dissipation California	46246517	264	OWN	200081
835.6100	Field dissipation Georgia	46246518	264	OWN	110899
835.6100	Field dissipation New York	46246519	264	OWN	200083
835.6100	Field dissipation Saskatchewan	46246520	264	OWN	200134
835.6100	Field dissipation Manitoba - JAU	46246521	264	OWN	200096
835.6100	Storage stability soil	46246525	264	OWN	MR-644/99
835.6100	Field Dissipation Europe	46246526	264	OWN	MR-215/98
835.6100	Storage stability triazole in soil	46246538	264	OWN	108103
835.6100	Storage stability soil - JAU & metabolites	46246544	264	OWN	MK061102
835.6200	Aquatic field dissipation California	46246522	264	OWN	200080
835.6200	Aquatic field dissipation Arkansas	46246523	264	OWN	200081
835.6200	Aquatic field dissipation Arkansas	46246524	264	OWN	200082
835.None	ILV for JAU and metabolites in water	46246527	264	OWN	200484
835.None	ILV for triazole in water	46246528	264	OWN	200483
835.None	ILV for JAU and metabolites in soil	46246529	264	OWN	200482
835.None	ILV for triazole in soil	46246530	264	OWN	200481

Signature: [signature]	Name and Title: Jessica Fernandes, Registration Manager	Date: May 18, 2012

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Date: May 18, 2012	EPA Reg. No./File Symbol: 264-824	Page: 1 of 27
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835 None	Soil multiresidue method – JAU & metabolites	46246531	264	OWN	200515
835 None	Soil and sediment method - triazole	46246532	264	OWN	200518
835 None	Water method triazole	46246533	264	OWN	200519
835 None	Soil Koc- JAU	46246534	264	OWN	200813
835 None	Water & sediment method – JAU & metabolites	46246535	264	OWN	200517
835 None	Temperature referenced field half-lives – JAU & SXX	46246536	264	OWN	200321
835 None	Aquatic Environment and Drinking Water Exposure Assessment of JAU 6476 & Major Metabolites	46246537	264	OWN	200840
835 None	Degradation of JAU6476 & its major metabolites in two sediment-water systems under aerobic conditions	46246540	264	OWN	200841
835 None	Aquatic Environmental and Drinking Water Assessment of Prothioconazole and Major Metabolites Resulting from Prothioconazole Use on Rice	48034803	264	OWN	MEJAY008
835 None	Aquatic Ecological & drinking water exposure assessment for JAU 6476 & its major metabolites resulting from JAU 6476 use on barley, canola, soybean, peanut & wheat	46246541	264	OWN	200842
835 None	Soil method – JAU & metabolites	46246543	264	OWN	MR-04399
835 None	Calculation of half-life in soil	46246546	264	OWN	MR-383/01
835 None	Tier II summaries for environmental fate studies	46246547	264	OWN	201089

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.None	Environmental Fate and Ecolog. Risk Assessment Streams: Rice and Seed Treatment Uses	46136701	264	OWN	C00146
Ecological Effects Data Requirements					
850.1010	Invertebrates toxicity – 480 SC	46246009	264	OWN	HBF DM 212
850.1010	Invertebrates toxicity – JAU	46246010	264	OWN	200513
850.1010	Invertebrates toxicity – SXX	46246011	264	OWN	HBF DM 95
850.1010	Invertebrates toxicity – S-Methyl	46246012	264	OWN	DOM 21055
850.1010	Invertebrates toxicity – SXX	46246013	264	OWN	200985
850.1025	Estuarine/marine tox. mollusk – JAU	46246014	264	OWN	110956
850.1025	Seabed ... marine ... – JAU	46246015	264	OWN	110957
850.1035	Estuarine/marine tox. shrimp – JAU	46246016	264	OWN	110953
850.1035	Estuarine/marine tox. shrimp – SXX	46246017	264	OWN	110919
850.1075	Fish toxicity trout – JAU	46246018	264	OWN	DOM 99027
850.1075	Fish toxicity trout – 480 SC	46246019	264	OWN	200697
850.1075	Fish toxicity trout – SXX	46246020	264	OWN	FF-297
850.1075	Fish toxicity trout – S-Methyl	462460[illegible]	264	OWN	DOM 21047
850.1075	Fish toxicity bluegill LC50 – JAU	46246022	264	OWN	DOM 99090
850.1075	Fish toxicity bluegill – 480 SC	46246023	264	OWN	200509

Signature: [signature]	Name and Title: Jessica Fernandez, Registration Manager	Date: May 16, 2011

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1075	Fish toxicity trout – SXX	46246024	264	OWX	EO-C253
850.1075	Fish toxicity carp – IAL	46246025	264	OWX	DOM 20010
850.1075	Fish toxicity fathead minnow – SXX	46246026	264	OWX	200151
850.1075	Fish toxicity sheepshead minnow – IAL	46246027	264	OWX	200815
850.1300	Chronic toxicity daphnia	46246028	264	OWX	HDB-RDB 67
850.1300	Chronic toxicity daphnia – SXX	46246029	264	OWX	DOM 21036
850.1350	Invertebrates life cycle, marine – SXX	46246030	264	OWX	200815
850.1400	Fish early life stage, freshwater – IAL	46246031	264	OWX	DOM 20028
850.1400	Fish early life stage, freshwater – SXX	46246032	264	OWX	HC2.81.2.321
850.1500	Fish life cycle, fathead minnow – SXX	46246033	264	OWX	200108
850.1730	Fish BCF – IAL	46246034	264	OWX	DOM 21003
850.1730	Fish BCF – SXX	46246035	264	OWX	DOM 20006
850.2100	Acute avian oral LD50 quail – IAL	46246036	264	OWX	BAR/LD 028
850.2100	Acute avian oral LD50 quail – SXX	46246037	264	OWX	VB-009
850.2100	Acute avian oral LD50 Canary (passerine)	48024801	264	OWX	EBIAL065
850.2200	Avian dietary LC50 Quail	46246038	264	OWX	BAR/LC 094
850.2300	Avian reproduction, quail – SXX	46246039	264	OWX	BAR/LC 011
850.2300	Avian reproduction, duck – IAL	4624604[illegible]	264	OWX	BAR/LC 010

Signature: [signature]

Name and Title: [illegible] Fernandez, Registration Manager

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole; 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian analytical method – SXX	46246041	264	OWN	110161
850.2300	Avian reproduction, quail – JAU	46246042	264	OWN	250842
850.2300	Avian reproduction, quail – SXX	46246043	264	OWN	BAR/REP006
850.2300	Avian reproduction, duck – JAU	46246044	264	OWN	250019
850.2300	Avian reproduction, duck – SXX	46246045	264	OWN	110617
850.3020	Acute toxicity/honey bee – 480 SC	46246046	264	OWN	18353023
850.3020	Parasitoid *Aphidius rhopalosiphi* – 480 SC	46246047	264	OWN	18352002
850.3020	Acute toxicity/honey bee – JAU	46246048	264	OWN	IBA 60051
850.4000	Non-target plant testing – 480 SC	46246049	264	OWN	200951
850.4100	Seedling emergence, Tier 1 – 480 SC	46246049	264	OWN	200951
850.4150	Vegetative vigor, Tier 1 – 480 SC	46246049	264	OWN	200951
850.4000	Non-target plant testing – 480 SC	46246050	264	OWN	200952
850.4225	Seedling emergence, Tier 2 – 480 SC	46246050	264	OWN	200952
850.4250	Vegetative vigor, Tier 2 – 480 SC	46246060	264	OWN	200952
850.4400	Aquatic plant growth, duckweed – JAU	46246101	264	OWN	200488
850.4400	Aquatic Plant Growth, duckweed – 480 SC	46246102	264	OWN	200672
850.4400	Aquatic Plant Growth, bluegreen algae – JAU	46246103	264	OWN	200497
850.4400	Aquatic plant growth – SXX	46246104	264	OWN	200469

Signature: [signature]

Name and Title: Jessica Fernandez, Registration Manager

Date: May 18, 2012

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Date: May 18, 2012	EPA Reg. No./File Symbol: 264-825 Page 17 of 27
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.5400	Algae toxicity, *Selenastrum* (green algae) – JAU	46246105	264	OWN	DOM 99107
850.5400	Algae toxicity, *Pseudokirchneriella* (green algae) – 480 SC	46246106	264	OWN	[illegible]
850.5400	Algae toxicity, *Selenastrum* (green algae) – S-Methyl	46246107	264	OWN	DOM 21028
850.5400	Algae toxicity, *Scenedesmus* (green algae) – SXX	46246108	264	OWN	HBF/AL 78
850.5400	Algae toxicity, *Navicula* – JAU	46246109	264	OWN	[illegible]
850.5400	Algae toxicity, *Anabaena* – JAU	46246110	264	OWN	[illegible]
850.None	Predatory mite – JAU	46246111	264	OWN	[illegible]
850.None	Soil microbial mineralization – JAU	46246112	264	OWN	AJO/203199
850.None	Soil glucose stimulated respiration – JAU	46246113	264	OWN	AJO/203099
850.None	Soil microbial mineralization – SXX	46246114	264	OWN	AJO/209400
850.None	Soil microbial mineralization – SXX	46246115	264	OWN	AJO/219101
850.None	Soil microbial mineralization – S-Methyl	46246116	264	OWN	AJO/203399
850.None	Soil glucose stimulated respiration – S-Methyl	46246117	264	OWN	AJO/203398
850.None	Reproduction Toxicity, *Folsomia* – JAU	46246118	264	OWN	[illegible]
850.None	Reproduction Toxicity, *Folsomia* – SXX	46246119	264	OWN	[illegible]
850.None	Reproduction Toxicity, *Folsomia* – SXX	46246120	264	OWN	[illegible]
850.None	Reproduction Toxicity, *Folsomia* – S-Methyl	46246121	264	OWN	[illegible]
850.None	Acute toxicity, earthworm – JAU	46246122	264	OWN	[illegible]

Signature: [signature]	Name and Title: Jessica Fernandez, Registration Manager	Date: May 18, 2012

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.None	Acute toxicity earthworm – EC 250	46246123	264	OWN	MPF/Rg 731/00
850.None	Acute toxicity earthworm – 480 SC	46246124	264	OWN	LKC/Rg-A 10/03
850.None	Acute toxicity earthworm – SXX	46246125	264	OWN	MPF/Rg 159/00
850.None	Chronic toxicity earthworm – S-Methyl	46246126	264	OWN	HBF/Rg 321
850.None	Chronic toxicity earthworm – EC 250	46246127	264	OWN	MPF/Rg 123/00
850.None	Chronic toxicity earthworm – SXX	46246128	264	OWN	MPF/Rg 332/00
850.None	Acute toxicity earthworm – S-Methyl	46246129	264	OWN	HBF/Rg 317
850.None	Earthworm fauna in grassland area – EC 250	46246130	264	OWN	LKC/Rg-F 34
850.None	Development & emergence *Chironomus riparius* – JAU	46246131	264	OWN	HDB/Ch 42
850.None	Development & emergence *Chironomus riparius* – SXX	46246132	264	OWN	HDB/Ch 43
850.None	*Chironomus* sediment full life-cycle study, SXX, OECD Guideline 218	47620901	264	OWN	E6JAY008
850.None	Wildlife residue wheat – 480 SC	46246133	264	OWN	111093
850.None	Wildlife residue corn – 480 SC	46246134	264	OWN	200873
850.None	Wildlife residue peanut – 480 SC	46246135	264	OWN	200833
850.None	Earthworm fauna in grassland area – EC 250	46246136	264	OWN	MO-02-014407
850.None	Effects on predatory mite *Typhlodromus pyri* – 480 SC	46246137	264	OWN	18353002
850.None	Environmental Risk Assessment – JAU	46246139	264	OWN	201000

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Name and Title: Jessica Fernandez, Registration Manager

Date: May 18, 2012

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Date: May 18, 2012		EPA Reg. No./File Symbol: 264-824	Page: 14 of 27
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole; 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.None	Tier II Summaries for Ecotoxicology Studies - IAU	46246140	264	OWN	201002
850.None	Ecotox Risk assessment for rice	48024802	264	OWN	US0017
850.None	Environmental Fate and Ecotox Risk assessment Nursery, Rice, and Seed Treatment Uses	48538701	264	OWN	US0196
Residue Chemistry Data Requirements					
860.1300	Nature of residue, wheat - IAU	46246141	264	OWN	110880
860.1300	Nature of residue, wheat, seed treatment - IAU	46246142	264	OWN	110881
860.1300	Nature of residue, wheat - triazole label - IAU	46246143	264	OWN	200731
860.1300	Nature of residue, wheat - SXX	46246144	264	OWN	MR-PF 3986
860.1300	Nature of residue, peanuts - phenyl label - IAU	46246145	264	OWN	MR-193/01
860.1300	Nature of residue, peanuts - triazole label - IAU	46246146	264	OWN	MR-194/02
860.1300	Nature of residue, sugar beet - triazole label - IAU	46246147	264	OWN	200467
860.1300	Nature of residue, sugar beet - phenyl label - IAU	46246148	264	OWN	200466
860.1300	Nature of residue, goat - triazole label - IAU	46246149	264	OWN	MR-449/02
860.1300	Nature of residue, goat - phenyl label - IAU	46246150	264	OWN	MR-492/01
860.1300	Nature of residue, goat - phenyl label (dethio) - SXX	46246201	264	OWN	MR-491/01
860.1300	Nature of residue, poultry - phenyl label - IAU	46246202	264	OWN	MR-308/01
860.1300	Nature of residue, poultry - triazole label - IAU	46246203	264	OWN	MEF-005/03

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6	

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300	TRR in alfalfa – seed treatment	48024901	264	OWN	MEEEP111
860.1300	TRR in potato – seed treatment	48024902	264	OWN	MEEEP091
860.1340	Animal method – JAU & metabolites – JAU & metab	46246204	264	OWN	200557
860.1340	Animal method – JAU metabolites	46477704	264	OWN	MR-517/00
860.1340	Animal method – LC/MS/MS	47953501	264	OWN	JA-010-A10-01
860.1340	Animal method, extraction efficiency – JAU & metab	46246205	264	OWN	MEF-020/04
860.1340	Crop residue method validation – JAU & metabolites	46246206	264	OWN	200799
860.1340	Animal method ILV	46246207	264	OWN	RAJAY004
860.1340	Crop method extraction efficiency	46246208	264	OWN	RAJAY011
860.1340	Crop residue method ILV	46246209	264	OWN	RAJAY020
860.1340	Crop method HPLC-MS/MS cereals JAU & SXX	46477702	264	OWN	MR-401/99
860.1340	Crop method HPLC-MS/MS cereals JAU & SXX (method modification 00598/M001)	46477703	264	OWN	MR-688/99
860.1340	Crop method – LC/MS/MS	47948901	264	OWN	JA-005-P09-02
860.1360	Method multi-residue	46246210	264	OWN	200980
860.1380	Storage stability in crop matrices (6-month data)	46246211	264	OWN	200824
860.1380	Storage stability in crop sufficiency study	46477701	264	OWN	201362
860.1380	Storage Stability in crops	47408201	264	OWN	RAJAY016

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1380	Storage Stability with the residue trials – JAU & SXX	46246139	264	OWN	MR-95/401
860.1380	45-day fat storage stability data	47107801	264	OWN	RAJAY040
860.1380	Storage stability triazole	47606601	US Triazole Task Force	Member	RAJAY[illegible]
860.1480	Feeding study, cattle – JAU	46246213	264	OWN	200913
860.1480	Feeding study, cattle – SXX	46246214	264	OWN	MR-535/00
860.1480	Feeding study, poultry – JAU	47492801	264	OWN	RAAAL001
860.1500	Crop field study, barley	46246220	264	OWN	200006
860.1500	Crop field study, [illegible]	[illegible]	264	OWN	[illegible]
860.1500	Crop field study, canola	46246215	264	OWN	200461
860.1500	Crop field study, corn	47521901	264	OWN	RAAAP004
860.1500	Crop field study, corn ULV	48116901	264	OWN	RAAAP020-1
860.1500	Crop field study, corn seed treatment	48516202	264	OWN	RA-2567/07
860.1500	Crop field study, corn seed treatment	48516203	264	OWN	RA-6220/06
860.1500	Crop field study, corn seed treatment	48516204	264	OWN	RA-2596/07
860.1500	Crop field study, corn seed treatment	48516205	264	OWN	RA-2621/06
860.1500	Crop field study, [illegible]	[illegible]	264	OWN	[illegible]
860.1500	Crop field study, [illegible] vegetables	[illegible]	264	OWN	[illegible]

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[signature]	[illegible], Registration Manager	May 18, 2012

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Crop field study, peanut	46246217	264	OWN	200509
860.1500	Crop field study, peanut – bridging study (seed, soil, foliar)	47214901	264	OWN	RAJAY005
860.1500	Crop field study, peas & beans, dried	46246221	264	OWN	200936
860.1500	Potato – EU seed treatment	48024903	264	OWN	RA-2559/05
860.1500	Potato – EU seed treatment	48024904	264	OWN	RA-2604/05
860.1500	Crop field study, rice	46246216	264	OWN	200468
860.1500	Crop field study, soybean	46841001	264	OWN	RAAAY002
860.1500	Crop field study, sugar beets	46974808	264	OWN	RAAAY004
860.1500	Crop field study, wheat	46246218	264	OWN	200521
860.1500	Crop field study, canola	46246219	264	OWN	200524
860.1500	Crop field study, wheat – bridging study (seed, soil, foliar)	47227008	264	OWN	RAJAY007
860.1500	Crop field study wheat – translate from foliar to seed treatment uses on other crops	48024905	264	OWN	MEJAY007
860.1500	Crop field study corn and wheat – translate from foliar to seed treatment use on other crops	48516201	264	OWN	MEJAY007-11
860.1520	Processing study, canola	46246224	264	OWN	200053
860.1520	Processing study, corn	47521903	264	OWN	RAJAP001
860.1520	Processing study, peanut	46246223	264	OWN	200518
860.1520	Processing study, rice	46246222	264	OWN	200491

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Processing study, soybean	[illegible]	264	OWN	RAJAY027
860.1520	Processing study, sugar beets	[illegible]	264	OWN	RAJAY023
860.1520	Processing & Crop field study, wheat	[illegible]	264	OWN	200521
860.1850	Confined rotational crop - phenyl label	46246225	264	OWN	110082
860.1850	Confined rotational crop - triazole label	46246226	264	OWN	200623
860.1900	Field rotational crop	46246227	264	OWN	200535
860 None	Dietary exposure assessment, acute & chronic	46246228	264	OWN	200996
860 None	Tier II Summaries for Residue Chemistry Studies	46246229	264	OWN	201009
Toxicology Data Requirements					
870.1100	Acute oral toxicity, rat - JAU	46246230	264	OWN	00946
870.1100	Acute oral toxicity, rat - SXX	46246231	264	OWN	109274
870.1100	Acute oral toxicity, rat - JAU asymmetric [illegible]	46246232	264	OWN	12123
870.1100	Acute oral toxicity, rat - JAU des-chloro	46246234	264	OWN	ATO0329
870.1100	Acute oral toxicity, rat - JAU methyl	46246235	264	OWN	[illegible]
870.1100	Acute oral toxicity, rat - JAU asymmetric [illegible]	46246236	264	OWN	11498
870.1100	Acute oral toxicity, rat - JAU sulfonic acid K salt	46246237	264	OWN	30277
870.1100	Acute oral toxicity, rat - JAU alpha-hydroxy-desthio	46246238	264	OWN	30109
870.1100	Acute oral toxicity, rat - JAU alpha-acetoxy-desthio	46246239	264	OWN	30110

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Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1000	Acute oral toxicity, rat - JAU [illegible]	46246240	264	OWN	29906
870.1100	Acute oral toxicity, rat - JAU [illegible]	46246241	264	OWN	30108
870.1100	Acute oral toxicity, mouse - SXX	46246242	264	OWN	109278
870.1200	Acute dermal toxicity, rat - SXX	46246243	264	OWN	109276
870.1200	Acute dermal toxicity, rat - JAU	46246244	264	OWN	108994
870.1300	Acute inhalation Toxicity, rat - JAU	46246246	264	OWN	109267
870.1300	Acute inhalation Toxicity, rat - SXX	46246247	264	OWN	109275
870.2400	Primary eye irritation, rabbit - JAU	46246298	264	OWN	108997
870.2400	Primary eye irritation, rabbit - SXX	46246299	264	OWN	108969
870.2500	Primary dermal irritation, rabbit - JAU	46246302	264	OWN	108998
870.2500	Primary dermal irritation, rabbit - SXX	46246250	264	OWN	108969
870.2600	Skin sensitization, guinea pig - SXX	46246304	264	OWN	109277
870.2600	Skin sensitization, guinea pig - JAU	46246305	264	OWN	108999
870.2600	Skin sensitization, guinea pig - JAU des-chloro	46246307	264	OWN	AT00031
870.2600	Skin sensitization, guinea pig 1-Chloro-2,4-dinitrobenzol	46246308	264	OWN	19316
870.3100	90-day oral toxicity rat - SXX	46246309	264	OWN	109446
870.3100	Rodent Range-finding study - SXX	46246310	264	OWN	109445 & 109445-1
870.3100	90-day oral toxicity rat - JAU	46246311	264	OWN	109095

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Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione. CAS No: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.SUPP	Supplemental study for 90-day oral toxicity rat - JAU	48020410	264	OWN	27581
870.SUPP	Supplemental study for 90-day oral toxicity rat - JAU	48020403	264	OWN	26844
870.SUPP	Supplemental study for 90-day oral toxicity rat - JAU	48020407	264	OWN	26807
870.SUPP	Supplemental study for 90-day oral toxicity rat - JAU	48020409	264	OWN	27046
870.SUPP	Supplemental study for 90-day oral toxicity rat - JAU	48020405	264	OWN	26902
870.SUPP	Supplemental study for 90-day oral toxicity rat - JAU	48020406	264	OWN	27874
870.3100	90-day oral toxicity rat - JAU sulfonic acid K salt	46246312	264	OWN	[illegible]
870.3150	90-day feeding study dog - JAU	46246313	264	OWN	109443
870.3150	90-day feeding study dog - SXX	46246314	264	OWN	29616
870.3200	21-day dermal toxicity - JAU	46246315	264	OWN	30112
870.3700	Developmental toxicity rat - JAU	46246316	264	OWN	109074
870.3700	Developmental toxicity rat - JAU desthio	46246317	264	OWN	[illegible]
870.3700	Developmental toxicity rat - JAU sulfonic acid K salt	[illegible]	264	OWN	[illegible]
870.3700	Developmental toxicity rat - SXX	46246319	264	OWN	109288
870.3700	Developmental toxicity rat - SXX	46246320	264	OWN	18641
870.3700	Developmental toxicity rat - SXX	46246321	264	OWN	108979
870.3700	Developmental toxicity rat - SXX	46246322	264	OWN	108979-1
[illegible]	Developmental [illegible] - JAU	[illegible]	264	OWN	[illegible]

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3700	Developmental toxicity rat - JAU sulfonic acid K salt	46246324	264	OWN	82991
870.3700	Developmental dermal toxicity rat - SXX	46246325	264	OWN	109289
870.3700	Developmental dermal toxicity rat - SXX	46246326	264	OWN	109289-1
870.3700	Supplemental pre-natal developmental toxicity rat	46923601	264	OWN	201037
870.3700	Developmental toxicity rabbit - SXX	46246327	264	OWN	109270
870.3700	Developmental toxicity rabbit - JAU	46246328	264	OWN	108637
870.3700	Developmental dermal toxicity rabbit - SXX	46246329	264	OWN	85823
870.3700	Developmental toxicity rabbit - JAU	46246330	264	OWN	87001
870.3800	Reproduction/fertility rat - JAU	46246331	264	OWN	109079
870.3800	Reproduction/fertility rat - SXX	46246332	264	OWN	103274
870.3800	Reproduction/fertility rat - SXX	46246333	264	OWN	109835
870.3800	Reproduction/fertility rat - JAU	46246334	264	OWN	110900
870.4100	Rat chronic - JAU	46246335	264	OWN	30536
870.4100	Dog chronic - JAU	46246336	264	OWN	110923
870.4100	Dog chronic - SXX	46246337	264	OWN	31138
870.4200	Carcinogenicity rat - JAU	46246338	264	OWN	31512
870.4200	Carcinogenicity mouse - JAU	46246339	264	OWN	31810
870.4200	Carcinogenicity mouse - SXX	46246340	264	OWN	30045

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Date: May 18, 2012	EPA Reg. No./File Symbol: 264-824	Page 12 of 27
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.4200	Carcinogenicity mouse - SXX	46246341	264	OWN	000851
870.4300	Chronic toxicity/carcinogenicity rat - SXX	46246342	264	OWN	100447
870.5100	Gene mutation, Ames - JAU	46246343	264	OWN	109055
870.5100	Gene mutation, Ames - SXX	46246344	264	OWN	108970
870.5100	Gene mutation, Ames - JAU desthio	46246345	264	OWN	AT00004
870.5100	Gene mutation, Ames - JAU - methyl	46246346	264	OWN	L267
870.5100	Gene mutation, Ames - JAU - symmetric isomer	46246347	264	OWN	12001
870.5100	Gene mutation, Ames - JAU - symmetric disulfide	46246348	264	OWN	11563
870.5100	Gene mutation, Ames - JAU - alpha hydroxy-desthio	46246349	264	OWN	10066
870.5100	Gene mutation, Ames - JAU - triazolinone	46246350	264	OWN	10063
870.5100	Gene mutation, Ames - JAU alpha-acetoxy-desthio	46246401	264	OWN	10004
870.5100	Gene mutation, Ames - JAU sulfonic acid K salt	46246402	264	OWN	29969
870.5100	Gene mutation, Ames - JAU thioxylpropylthiol	46246403	264	OWN	19700
870.5300	Cell Gene mutation - JAU	46246404	264	OWN	109056
870.5300	Cell Gene mutation - SXX	46246405	264	OWN	109264
870.5375	Chromosome aberration test - JAU	46246406	264	OWN	109051
870.5375	Chromosome aberration test - SXX	46246407	264	OWN	108971
870.5375	Chromosome aberration test - JAU desthio	46246408	264	OWN	AT00021

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5395	Micronucleus Test - JAU	46246409	264	OWN	109059
870.5395	Micronucleus Test - SXX	46246410	264	OWN	108934
870.5395	Micronucleus Test - JAU	46246411	264	OWN	110250
870.5550	Unscheduled DNA Synthesis - JAU	46246412	264	OWN	109080
870.5550	Unscheduled DNA Synthesis - JAU	46246413	264	OWN	109253
870.5550	Unscheduled DNA Synthesis - SXX	46246414	264	OWN	108973
870.5550	[illegible] - JAU	46246415	264	OWN	[illegible]
870.6200	Subchronic neurotoxicity screen rat - JAU	46246416	264	OWN	[illegible]
870.6200	Acute neurotoxicity screen rat - JAU	46246417	264	OWN	109250
870.6300	Developmental Neurotoxicity Screen rat - SXX	46246418	264	OWN	200958
870.6300	Developmental Neurotoxicity Screen rat - SXX - brain morphometric data	47293901	264	OWN	200958-1
870.7485	Metabolism rat - JAU	46246419	264	OWN	MR-457/01
870.7485	Metabolism rat - SXX	46246420	264	OWN	PF 3554
870.7485	Metabolism rat - JAU triazole & phenyl label	46246421	264	OWN	MR-251/01
870.7485	Metabolism rat - SXX [illegible]	46246422	264	OWN	MR-056/01
870.7600	Dermal penetration monkeys - JAU	46246423	264	OWN	200363
870.7600	Dermal penetration monkeys - SXX	46246424	264	OWN	200480

Signature: [signature]

Name and Title: Jessica Fernandez, Registration Manager

Date: May 18, 2012

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DATA MATRIX

Date: May 16, 2012

EPA Reg. No./File Symbol: 264-824

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7600	Dermal penetration monkeys - SXX to SC480	46246425	264	OWN	200443
870.7600	Dermal penetration monkeys - JAU, 250 EC, pilot	46246426	264	OWN	MR-545/97
870.7800	Immunotoxicity - [illegible]	48020401	264	OWN	031018
870.None	Range-finding study in CD-1 mice - JAU	46246427	264	OWN	109063
870.None	Subacute oral, rat - JAU	46246428	264	OWN	109061
870.None	Subacute oral, rat - JAU	46246429	264	OWN	109062
870.None	Subacute oral, rat - SXX	46246430	264	OWN	109271
870.None	Subacute oral, dog - SXX	46246431	264	OWN	109272
870.None	Subacute inhalation, rat - SXX	46246432	264	OWN	109273
870.None	Subacute inhalation, rat - SXX	46246433	264	OWN	109283
870.None	Acute intraperitoneal - SXX	46246434	264	OWN	109279
870.None	Mechanistic/metabolic dog - JAU	46246435	264	OWN	30260
870.None	Thyroid peroxidase-catalyzed reaction - JAU	46246436	264	OWN	25157
870.None	Liver foci test - SXX	46246437	264	OWN	29880
870.None	Plaque-forming cell assay in mice - JAU	46246438	264	OWN	32090
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020408	264	OWN	31085
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020402	264	OWN	AT00215
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	48020403	264	OWN	29004

Signature: [signature]

Name and Title: Jessica Fernandez, Registration Manager

Date: May 16, 2012

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DATA MATRIX

Date: May 18, 2012	EPA Reg. No./File Symbol: 264-824	Page [illegible] of 37
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	[illegible]	264	OWN	29019
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46193201	264	OWN	[illegible]-30640
870.None	Plasma kinetics - SXX	46246439	264	OWN	[illegible]
870.None	Analytical LC method for dose determinations - JAU	46246440	264	OWN	108084
870.None	Assessment of ovarian findings in rodents - SXX	46246441	264	OWN	M[illegible]-000457
870.None	Validation of the Magnusson-Kligman Maximization Test Method	46246442	264	OWN	29609
870.None	Validation of the Magnusson-Kligman Maximization Test Method	46246443	264	OWN	A[illegible]
870.None	Analytical LC method in plasma samples - SXX	46246444	264	OWN	101238
870.None	Tier II Summaries for Toxicology Studies	46246445	264	OWN	201033
Occupational & Residential Exposure					
875.2100	Foliar dislodgeable residue	46979102	264	OWN	Preliminary RAAAY028
875.2100	Foliar dislodgeable residue	47003601	264	OWN	RAAAY028
875.2100	Foliar dislodgeable residue	47023601	264	OWN	RAAAY028-1
875.Group A and B	Occupational Exposure and Safety Assessment for Prothioconazole	46246446	264	OWN	200953
875.Group A and B	Assessment of the Non-Dietary Exposure From the Addition of [illegible] and [illegible]	[illegible]	264	OWN	

Signature: [signature]	Name and Title: [illegible], Registration Manager	Date: May 18, 2012

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DATA MATRIX

Date: May 18, 2012		EPA Reg. No./File Symbol: 264-824	Page [illegible] of 27
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione. CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875 Group A and B	Assessment of Non-Dietary Exposure on sweet, pop, and field corn	47521906	264	OWN	G201925
875 Dermal	Determination of Exposure to JAU 6476 & JAU 6476 desthio (SXX0665) During Mixing/Loading & Application of JAU 6476 in Cereals	46246447	264	OWN	MR-036012
875 Both	Determination of Exposure to JAU 6476 & JAU 6476 desthio (SXX0665) During Mixing/Loading & Application of JAU 6476 in Cereals – Raw Data	47337401	264	OWN	MR-036012-1
875 None	Tier II Summaries for Occupational and Residential Exposure	46246448	264	OWN	201096
1,2,4-Triazole and Derivatives		Cite-all	US Triazole Task Force	Member	
Spray Drift Data Requirements		Cite-all	Spray Drift Task Force	Member	
Reentry Data Requirements					
875 Group B	Residential exposure	Cite-all	Outdoor Residential Exposure Task Force	Member	

Signature	Name and Title	Date
[signature]	Jessica Fernandez, Registration Manager	May 18, 2012

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Date: May 18, 2012		EPA Reg. No./File Symbol: 264-824	Page 27 of 27
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875 Group B	Reentry exposure	Cite all	Agricultural Reentry Task Force	Member	
875 Group A	Handler exposure data	Cite all	Agricultural Handlers Exposure Task Force	Member	
Miscellaneous					
None	Tier III Summaries, Prothioconazole	46246548	264	OWN	
None	Proposal to Revise Application Pattern for Soybean	46706601	264	OWN	
None	Public Interest Document	46765801	264	OWN	PD - 8/31/05(N)13

Signature: [illegible]	Name and Title: Jessica Fernandes, Registration Manager	Date: May 18, 2012

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Exhibit 14

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DATA MATRIX

Date: March 31, 2010		EPA Reg. No./File Symbol: 264-824 Page 1 of 31
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole; 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy Data					
810.None	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 1-Wheat	46245805	264	DWH	
810.None	Prothioconazole Fusarium head blight deficiency response in wheat	46477705	264	DWH	
810.New	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 2-Barley	46245805	264	DWH	
810.None	Prothioconazole Fusarium head blight deficiency response in barley	46477703	264	DWH	
810.None	Prothioconazole 480 SC Fungicide for control of diseases in pulse crops, cereal crops, canola & rapeseed Volume 3-Canola	46245807	264	DWH	
810.None	Prothioconazole 480 SC Fungicide for Control of Diseases in Pulse Crops, Cereal Crops, Canola and Rapeseed Volume 4-Chickpea	46245808	264	DWH	
Product Chemistry Data Requirements					
830.1550	Identity of ingredients	46245802	264	DWH	
830.1550	Identity of ingredients	46245801	264	DWH	

Signature: Melvin K. Tolmer	Name and Title: Melvin K. Tolmer, Registration Product Manager, Fungicides	Date: March 31, 2010

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Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824 Page: 3 of 3
Applicant's/Registrant's Name & Address: Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole; 2-[(2S)-1-(Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Identity of Ingredients	46477401	264	OWN	
830.1600	Description of Materials	45046002	264	OWN	
830.1600	Description of Materials	46246001	264	OWN	
830.1620	Description of Production Process	46246002	264	OWN	
830.1620	Description of Production Process	46246001	264	OWN	
830.1620	Description of Production Process	46477401	264	OWN	
830.1650	Description of Formulation Process	46246002	264	OWN	
830.1650	Description of Formulation Process	46246001	264	OWN	
830.1670	Formulation of Impurities	46246002	264	OWN	
830.1670	Formulation of Impurities	46246001	264	OWN	
830.1700	Preliminary Analysis	46246002	264	OWN	
830.1700	Preliminary Analysis	46246001	264	OWN	
830.1700	Preliminary Analysis	46477401	264	OWN	
830.1750	Certified limits	46246002	264	OWN	
830.1750	Certified Limits	46246001	264	OWN	
830.1800	Analytical Method	46246002	264	OWN	
830.1800	Analytical Method	46246001	264	OWN	

Signature: Melissa K. Tolliver	Name and Title: Melissa K. Tolliver, Registration Project Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824	Page 1 of 2
Applicant's/Registrant's Name & Address: Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,3-dihydro-3*H*-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800	Submittal of samples	46246002	264	OWN	
830.1800	Submittal of samples	46246001	264	OWN	
830.6302	Appearance	46246003	264	OWN	
830.6302	Appearance	46246001	264	OWN	
830.6303	Physical state	46246003	264	OWN	
830.6303	Physical state	46246001	264	OWN	
830.6304	Odor	46246003	264	OWN	
830.6304	Odor	46246001	264	OWN	
830.6313	Stability	46246003	264	OWN	
830.6313	Stability	46246001	264	OWN	
830.6314	Oxidizing or reducing potential	46246003	264	OWN	
830.6314	Oxidizing or reducing potential	46246001	264	OWN	
830.6315	Flammability	46246003	264	OWN	
830.6315	Flammability	46246001	264	OWN	
830.6316	Explosivity	46246003	264	OWN	
830.6316	Explosivity	46246001	264	OWN	
830.6317	Storage stability	46246003	264	OWN	

Signature: Melissa A. Tolliver	Name and Title: Melissa A. Tolliver, Registration Product Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-329	Page 1 of 2
Applicant's/Registrant's Name & Address: Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility	46246003	264	DWN	
830.6319	Miscibility	46246001	264	DWN	
830.6320	Corrosion characteristics	46246003	264	DWN	
830.6320	Corrosion characteristics	46246001	264	DWN	
830.6321	Dielectric breakdown	46246003	264	DWN	
830.6321	Dielectric breakdown	46246001	264	DWN	
830.7000	pH	46246003	264	DWN	
830.7000	pH	46246001	264	DWN	
830.7050	UV/visible absorption	46246002	264	DWN	
830.7050	UV/Visible absorption	46246001	264	DWN	
830.7100	Viscosity	46246002	264	DWN	
830.7100	Viscosity	46246001	264	DWN	
830.7200	Melting point	46246003	264	DWN	
830.7200	Melting point	46246001	264	DWN	
830.7220	Boiling point	46246003	264	DWN	
830.7220	Boiling point	46246001	264	DWN	
830.7300	Density, bulk density, or specific gravity	46246003	264	DWN	

Signature: Melvin K. Tillman	Name and Title: Melvin K. Tillman, Registration Review Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824	Page: 1 of 21
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[(2*RS*)-2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione; CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density, bulk density, or specific gravity	46248001	264	OWN	
830.7370	Dissociation constant	46248002	264	OWN	
830.7370	Dissociation constant	46248001	264	OWN	
830.7520	Particle size, fiber length, and diameter distribution	46248003	264	OWN	
830.7520	Particle size, fiber length, and diameter distribution	46248001	264	OWN	
830.7550	Octanol/water partition coefficient	46270403	264	OWN	
830.7550	Octanol/water partition coefficient	46248001	264	OWN	
830.7550	Octanol/water partition coefficient - pH 7	46270401	264	OWN	
830.7560	Octanol/water partition coefficient	46248003	264	OWN	
830.7560	Octanol/water partition coefficient	46248001	264	OWN	
830.7570	Octanol/water partition coefficient	46248003	264	OWN	
830.7570	Octanol/water partition coefficient	46248001	264	OWN	
830.7840	Solubility	46248003	264	OWN	
830.7840	Solubility	46248001	264	OWN	
830.7860	Solubility	46248003	264	OWN	
830.7860	Solubility	46248001	264	OWN	
830.7950	Vapor pressure	46248003	264	OWN	

Signature	Name and Title	Date
Melissa K. Tolliver	Melissa K. Tolliver, Registration Project Manager, Reregistration	March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-624	Page 6 of 24
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7950	Vapor pressure	46246601	264	OWN	
Environmental Fate Data Requirements					
835.1230	Soil adsorption/desorption – JAU	46246448	264	OWN	
835.1230	Soil adsorption/desorption – SAX	46246450	264	OWN	
835.1230	Soil adsorption/desorption – JAU 6-methyl	46246501	264	OWN	
835.1230	Soil adsorption/desorption – JAU 6-triazolone	46246502	264	OWN	
835.1240	Leaching Behavior – JAU	46246503	264	OWN	
835.1240	Aged column leaching – JAU	46246504	264	OWN	
835.1240	Parent column leaching – 250 EC	46246638	264	OWN	
835.2120	Hydrolysis – JAU (neryl)	46246505	264	OWN	
835.2120	Hydrolysis – SXX	46246506	264	OWN	
835.2240	Photodegradation in water – JAU	46246507	264	OWN	
835.2240	Photodegradation Quantum Yield & half life – JAU	46246508	264	OWN	
835.2240	Photodegradation Quantum Yield & half life – SXX	46246509	264	OWN	
835.2370	Photodegradation in air – JAU	46246510	264	OWN	
835.2370	Photodegradation in air – JAU 6-triazolone	46246511	264	OWN	
835.3410	Soil photolysis – JAU	46246516	264	OWN	

Signature	Name and Title	Date
[signature]	Melissa K. Tolliver, Registration Product Manager, Fungicides	March 31, 2010

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Date: March 31, 2010	EPA Reg. No./File Symbol: 264-833	Page: 3 of 20
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.2410	Photodegradation on soil	46358101	264	GWN	
835.4100	Aerobic soil metabolism – JAU	46206511	264	GWN	
835.4100	Aerobic soil metabolism – JAU	46246512	264	GWN	
835.4100	Aerobic soil metabolism – SXX	46246513	264	GWN	
835.4100	Aerobic soil metabolism – JAU, S-methyl	46246514	264	GWN	
835.4100	Aerobic soil metabolism	46358102	264	GWN	
835.4300	Aerobic aquatic metabolism – JAU	46246515	264	GWN	
835.4400	Anaerobic aquatic metabolism – JAU	46246516	264	GWN	
835.6100	Field dissipation California	46246517	264	GWN	
835.6100	Field dissipation Georgia	46246518	264	GWN	
835.6100	Field dissipation New York	46246519	264	GWN	
835.6100	Field dissipation Saskatchewan	46246520	264	GWN	
835.6100	Field dissipation Manitoba – JAU	46246521	264	GWN	
835.6100	Storage stability, soil	46246522	264	GWN	
835.6100	Field Dissipation Europe	46246523	264	GWN	
835.6100	Storage stability thiazole in soil	46246533	264	GWN	
835.6100	Storage stability, soil – JAU & metabolites	46246534	264	GWN	

Signature: Melvin K. Tolliver	Name and Title: Melvin K. Tolliver, Registration Product Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824 — Page 8 of 29
Applicant's/Registrant's Name & Address: Bayer CropScience, LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6200	Aquatic field dissipation California	46246522	264	OWN	
835.6200	Aquatic field dissipation Arkansas	46246523	264	OWN	
835.6200	Aquatic field dissipation Arkansas	46246524	264	OWN	
835.None	ILV for JAU and metabolites in water	46246527	264	OWN	
835. None	ILV for triazole in water	46246528	264	OWN	
835. None	ILV for JAU and metabolites in soil	46246529	264	OWN	
835. None	ILV for triazole in soil	46246530	264	OWN	
835.None	Soil multiresidue method – JAU & metabolites	46246531	264	OWN	
835.None	Soil and sediment method - triazole	46246532	264	OWN	
835.None	Water method triazole	46246533	264	OWN	
835.None	Soil Koc - JAU	46246534	264	OWN	
835.None	Water & sediment method – JAU & metabolites	46246535	264	OWN	
835.None	Temperature referenced field half-lives - JAU & SXX	46246536	264	OWN	
835.None	Aquatic Environment and Drinking Water Exposure Assessment of JAU 6476 & Major Metabolites	46246537	264	OWN	
835.None	Degradation of JAU6476 & its major metabolites in two sediment-water systems under aerobic conditions	46246540	264	OWN	

Signature: *Melissa K. Tollison*	Name and Title: Melissa K. Tollison, Regulatory Product Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824	Page: 9 of 24
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.None	Aquatic Environmental and Drinking Water Assessment of Prothioconazole and Major Metabolites Resulting from Prothioconazole Use on Rice	48024803	264	OWN	
835.None	Aquatic Ecological & drinking water exposure assessment for JAU 6476 & its major metabolites resulting from JAU 6476 use on barley, canola, dry bean, peanut & wheat	46246541	264	OWN	
835.None	Soil method – JAU & metabolites	46246543	264	OWN	
835.None	Calculation of half-life in soil	46246546	264	OWN	
835.None	Tier II summaries for environmental fate studies	46246547	264	OWN	
Ecological Effects Data Requirements					
850.1010	Invertebrates toxicity – 480 SC	46246009	264	OWN	
850.1010	Invertebrates toxicity – JAU	46246010	264	OWN	
850.1010	Invertebrates toxicity – SXX	46246011	264	OWN	
850.1010	Invertebrates toxicity – S-Methyl	46246012	264	OWN	
850.1010	Invertebrates toxicity – SXX	46246013	264	OWN	
850.1025	Estuarine/marine tox. mollusk – JAU	46246014	264	OWN	
850.1025	Method validation marine studies – JAU	46246015	264	OWN	
850.1035	Estuarine/marine tox. shrimp - JAU	46246016	264	OWN	

Signature: *Melvin K. Tolliver*	Name and Title: Melvin K. Tolliver, Registration Product Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824	Page 18 of 24
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione. CAS No. 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1035	Estuarine/marine tox. shrimp – SXX	46246017	264	OWN	
850.1075	Fish toxicity trout – JAU	46246018	264	OWN	
850.1075	Fish toxicity trout – 480 SC	46246019	264	OWN	
850.1075	Fish toxicity trout – SXX	46246020	264	OWN	
850.1075	Fish toxicity trout – S-Methyl	46246021	264	OWN	
850.1075	Fish toxicity bluegill LC50 – JAU	46246022	264	OWN	
850.1075	Fish toxicity bluegill – 480 SC	46246023	264	OWN	
850.1075	Fish toxicity orfe – SXX	46246024	264	OWN	
850.1075	Fish toxicity carp – JAU	46246025	264	OWN	
850.1075	Fish toxicity fathead minnow – SXX	46246026	264	OWN	
850.1075	Fish toxicity sheepshead minnow – JAU	46246027	264	OWN	
850.1300	Chronic toxicity daphnia	46246028	264	OWN	
850.1300	Chronic toxicity daphnia – SXX	46246029	264	OWN	
850.1350	Invertebrates life cycle, marine – SXX	46246030	264	OWN	
850.1400	Fish early life stage, freshwater – JAU	46246031	264	OWN	
850.1400	Fish early life stage, freshwater – SXX	46246032	264	OWN	
850.1500	Fish life cycle, fathead minnow – SXX	46246033	264	OWN	

Signature: Melvin G. Tolliver	Name and Title: Melvin G. Tolliver, Regulation Project Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-RXX	Page: 11 of 25
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014; 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[(2*R*)-1-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1730	Fish BCF – 3AU	46246083	264	OWN	
850.1730	Fish BCF – 3XX	46246084	264	OWN	
850.2100	Acute avian oral LD 50, quail – 3AU	46246036	264	OWN	
850.2100	Acute avian oral LD 50, quail – 3XX	46246037	264	OWN	
850.2100	Acute avian oral LD 50, Canary (passerine)	46024501	264	OWN	
850.2200	Avian dietary LC 50, Quail	46246038	264	OWN	
850.2200	Avian reproduction, quail – 3XX	46246039	264	OWN	
850.2200	Avian reproduction, duck – 3AU	46246040	264	OWN	
850.2100	Avian analytical method – 3XX	46246041	264	OWN	
850.2300	Avian reproduction, quail – 3AU	46246042	264	OWN	
850.2300	Avian reproduction, quail – 3XX	46246043	264	OWN	
850.2300	Avian reproduction, duck – 3AU	46246044	264	OWN	
850.2300	Avian reproduction, duck – 3XX	46246045	264	OWN	
850.3020	Acute toxicity honey bee – 480 SC	46246046	264	OWN	
850.3020	Parasitoid *Aphidius rhopalosiphi* – 480 SC	46246047	264	OWN	
850.3020	Acute toxicity honey bee – 3AU	46246048	264	OWN	
850.3030	Non-target plant testing – 480 SC	46246049	264	OWN	

Signature: Melvin A. Tolliver | Name and Title: Melvin A. Tolliver, Regulatory Project Manager, Fungicides | Date: March 31, 2010

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Date: March 31, 2010	EPA Reg. No./File Symbol: 264-[illegible]	Page: 3 of 2[illegible]
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1100	Seedling emergence, Tier 1 – 480 SC	46246048	264	OWN	
850.4250	Vegetative vigor, Tier 1 – 480 SC	46246049	264	OWN	
850.4000	Non-target plant testing – 480 SC	46246050	264	OWN	
850.4225	Seedling emergence, Tier 2 – 480 SC	46246050	264	OWN	
850.4250	Vegetative vigor, Tier 2 – 480 SC	46246060	264	OWN	
850.4400	Aquatic plant growth, duckweed – JAU	46246101	264	OWN	
850.4400	Aquatic Plant Growth, duckweed – 480 SC	46246102	264	OWN	
850.4400	Aquatic Plant Growth, bluegreen algae – JAU	46246103	264	OWN	
850.4400	Aquatic plant growth – SXX	46246104	264	OWN	
850.5400	Algae toxicity, *Selenastrum* (green algae) – JAU	46246105	264	OWN	
850.5400	Algae toxicity, *Pseudokirchneriella* (green algae) – 480 SC	46246106	264	OWN	
850.5400	Algae toxicity, *Selenastrum* (green algae) – S-Methyl	46246107	264	OWN	
850.5400	Algae toxicity, *Scenedesmus* (green algae) – SXX	46246108	264	OWN	
850.5400	Algae toxicity, *Navicula* – JAU	46246109	264	OWN	
850.5400	Algae toxicity, *Skeletonema* – JAU	46246110	264	OWN	
850/None	Predatory mite – JAU	46246111	264	OWN	
850/None	Soil microbial mineralization – JAU	46246112	264	OWN	

Signature: *Melvin K. Tolliver*	Name and Title: Melvin K. Tolliver, Registration Product Manager, Fungicides	Date: March 31, 2010

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Date: March 31, 2010 | EPA Reg. No./File Symbol: 264-825 | Page: 15 of 2?

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.None	Soil glucose stimulated respiration – JAU	46246113	264	OWN	
850.None	Soil microbial mineralization – SXX	46246114	264	OWN	
850.None	Soil microbial mineralization – SXX	46246115	264	OWN	
850.None	Soil microbial mineralization – S-Methyl	46246116	264	OWN	
850.None	Soil glucose stimulated respiration – S-Methyl	46246117	264	OWN	
850.None	Reproduction Toxicity, *Folsomia* – JAU	46246118	264	OWN	
850.None	Reproduction Toxicity, *Folsomia* – SXX	46246119	264	OWN	
850.None	Reproduction Toxicity, *Folsomia* – SXX	46246120	264	OWN	
850.None	Reproduction Toxicity, *Folsomia* – S-Methyl	46246121	264	OWN	
850.None	Acute toxicity earthworm – JAU	46246122	264	OWN	
850.None	Acute toxicity earthworm – EC 250	46246123	264	OWN	
850.None	Acute toxicity earthworm – 480 SC	46246124	264	OWN	
850.None	Acute toxicity earthworm – SXX	46246125	264	OWN	
850.None	Chronic toxicity earthworm – S-Methyl	46246126	264	OWN	
850.None	Chronic toxicity earthworm – EC 250	46246127	264	OWN	
850.None	Chronic toxicity earthworm – SXX	46246128	264	OWN	
850.None	Acute toxicity earthworm – S-Methyl	46246129	264	OWN	

Signature: Melvin K. Tolliver | Name and Title: Melvin K. Tolliver, Registration Product Manager, Fungicides | Date: March 31, 2010

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DATA MATRIX

Date: March 23, 2011	EPA Reg. No./File Symbol: 264-824	Page: 14 of 23
Applicant's/Registrant's Name & Address: Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2(2*R*)-2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-1,2-dihydro-3*H*-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.None	Earthworm fauna in grassland area – EC 250	46246130	264	OWN	
850.None	Development & emergence *Chironomus riparius* – JAU	46246131	264	OWN	
850.None	Development & emergence *Chironomus riparius* – EC	46246132	264	OWN	
850.None	Chironomus sediment full life-cycle study: SAX, OECD Guideline 218	47626901	264	OWN	
850.None	Wildlife residue wheat – 480 SC	46246133	264	OWN	
850.None	Wildlife residue turf – 480 SC	46246134	264	OWN	
850.None	Wildlife residue pasture – 480 SC	46246135	264	OWN	
850.None	Earthworm fauna in grassland area – EC 250	46246136	264	OWN	
850.None	Effects on predatory mite *Typhlodromus pyri* – 480 SC	46246137	264	OWN	
850.None	Environmental Risk Assessment – JAU	46246138	264	OWN	
850.None	Tier II Summaries for Ecotoxicology Studies - JAU	46246140	264	OWN	
850.None	Ecotox Risk Assessment for rice	43021902	264	OWN	
Residue Chemistry Data Requirements:					
860.1300	Nature of residue, wheat – JAU	46245141	264	OWN	
860.1300	Nature of residue, wheat, seed treatment – JAU	46245142	264	OWN	
860.1300	Nature of residue, wheat - residue level – JAU	46246143	264	OWN	

Signature: Helen K. Tolliver	Name and Title: Helen K. Tolliver, Registration Product Manager, Fungicides	Date: March 31, 2011

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824	Page 15 of 38
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300	Nature of residue: wheat – SXX	46246142	264	OWN	
860.1300	Nature of residue: peanuts – phenyl label – JAU	46246145	264	OWN	
860.1300	Nature of residue: peanuts – triazole label – JAU	46246146	264	OWN	
860.1300	Nature of residue: sugar beet – triazole label – JAU	46246147	264	OWN	
860.1300	Nature of residue: sugar beet – phenyl label – JAU	46246148	264	OWN	
860.1300	Nature of residue: goat – triazole label – JAU	46246149	264	OWN	
860.1300	Nature of residue: goat – phenyl label – JAU	46246150	264	OWN	
860.1300	Nature of residue: goat – phenyl label desthio – SXX	46246201	264	OWN	
860.1300	Nature of residue: poultry – phenyl label – JAU	46246202	264	OWN	
860.1300	Nature of residue: poultry – triazole label – JAU	46246203	264	OWN	
860.1300	TRR in alfalfa – seed treatment	46024501	264	OWN	
860.1300	TRR in potato – seed treatment	46024502	264	OWN	
860.1340	Animal method – JAU & metabolites – JAU & metab	46246204	264	OWN	
860.1340	Animal method – JAU metabolites	46247704	264	OWN	
860.1340	Animal method – LC/MS/MS	47053501	264	OWN	
860.1340	Animal method: extraction efficiency – JAU & metab	46246205	264	OWN	
860.1340	Crop residue method validation – JAU & metabolites	46246206	264	OWN	

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824	Page 1 of 2*
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione; CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Animal method ILV	46246307	264	OWN	
860.1340	Crop method extraction efficiency	46246208	264	OWN	
860.1340	Crop residue method ILV	46246309	264	OWN	
860.1340	Crop method HPLC-MS/MS cereals (JAU & SXX	46477702	264	OWN	
860.1340	Crop method HPLC-MS/MS cereals (JAU & SXX (method modification 00586/M001)	46477705	264	OWN	
860.1340	Crop method - LCMS/MS	47348901	264	OWN	
860.1360	Method multi-residue	46246310	264	OWN	
860.1380	Storage stability in crop matrices (6-month data)	46246311	264	OWN	
860.1380	Storage stability in crop deficiency study	46477701	264	OWN	
860.1380	Storage Stability in crops	47408201	264	OWN	
860.1380	Storage Stability: wildlife residue matr – JAU & SXX	46246139	264	OWN	
860.1380	45-day fat storage stability data	47107601	264	OWN	
860.1380	Storage stability matrix	47008501	US Triazole Task Force	Member	
860.1480	Feeding study, cattle – JAU	46246213	264	OWN	
860.1480	Feeding study, cattle – SXX	46246214	264	OWN	

Signature: Melvin K. Tolliver	Name and Title: Melvin K. Tolliver, Registration Branch Manager, Fungicides	Date: March 31, 2010

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Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1480	Feeding study, poultry – JAU	47459801	264	OWN	
860.1500	Crop field study, barley	46246220	264	OWN	
860.1500	Crop field study, canola	46246215	264	OWN	
860.1500	Crop field study, corn	47521901	264	OWN	
860.1500	Crop field study, peanuts	46246217	264	OWN	
860.1500	Crop field study, peanuts – bridging study (seed, soil, foliar)	47214701	264	OWN	
860.1500	Crop field study, peas & beans, dried	46246221	264	OWN	
860.1500	Potato – EU seed treatment	48024903	264	OWN	
860.1500	Potato – EU seed treatment	48024904	264	OWN	
860.1500	Crop field study, rice	46246216	264	OWN	
860.1500	Crop field study, soybean	46841801	264	OWN	
860.1500	Crop field study, sugar beets	46974805	264	OWN	
860.1500	Crop field study, wheat	46246218	264	OWN	
860.1500	Crop field study, wheat	46246219	264	OWN	
860.1500	Crop field study, wheat – bridging study (seed, soil, foliar)	47277008	264	OWN	
860.1500	Crop field study wheat – translate from foliar to seed treatment uses on other crops	48024905	264	OWN	

Signature: [signature]

Name and Title: [illegible] Tolliver, Regulatory Product Manager, Fungicides

Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010		EPA Reg. No./File Symbol: 264-824	Page 18 of 2[illegible]
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione. CAS No.: 178928-70-6			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1520	Processing study, canola	46246234	264	OWN	
860.1520	Processing study, corn	47521903	264	OWN	
860.1520	Processing study, peanut	46246223	264	OWN	
860.1520	Processing study, rice	46246222	264	OWN	
860.1520	Processing study, soybean	[illegible]	264	OWN	
860.1520	Processing study, sugar beets	[illegible]	264	OWN	
860.1520	Processing & Crop field study, wheat	46246218	264	OWN	
860.1850	Confined rotational crop – phenyl label	46246225	264	OWN	
860.1850	Confined rotational crop – triazole label	46246226	264	OWN	
860.1900	Field rotational crop	46246227	264	OWN	
860.None	Dietary exposure assessment, acute & chronic	46246228	264	OWN	
860.None	Tier II Summaries for Residue Chemistry Studies	46246220	264	OWN	
Toxicology Data Requirements					
870.1100	Acute oral toxicity, rat – JAU	46246230	264	OWN	
870.1100	Acute oral toxicity, rat – SXX	46246231	264	OWN	
870.1100	Acute oral toxicity, rat – JAU asymmetric isomer	46246233	264	OWN	
870.1100	Acute oral toxicity, rat – JAU desochloro	46246234	264	OWN	

Signature: *Melvin K. Tollner*	Name and Title: Melvin K. Tollner, Registration Project Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2019	EPA Reg. No./File Symbol: 264-824	Page 19 of 20
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute oral toxicity, rat – JAU methyl	46246235	264	OWN	
870.1100	Acute oral toxicity, rat – JAU asymmetric disulfide	46246236	264	OWN	
870.1100	Acute oral toxicity, rat – JAU sulfonic acid K salt	46246237	264	OWN	
870.1100	Acute oral toxicity, rat – JAU alpha-hydroxy desthio	46246238	264	OWN	
870.1100	Acute oral toxicity, rat – JAU alpha,beta-dioxy-desthio	46246239	264	OWN	
870.1100	Acute oral toxicity, rat – JAU benzylpropylidol	46246240	264	OWN	
870.1100	Acute oral toxicity, rat – JAU Mesalimene	46246241	264	OWN	
870.1100	Acute oral toxicity, mouse – SXX	46246242	264	OWN	
870.1200	Acute dermal toxicity, rat – SXX	46246243	264	OWN	
870.1200	Acute dermal toxicity, rat – JAU	46246244	264	OWN	
870.1300	Acute Inhalation Toxicity, rat – JAU	46246246	264	OWN	
870.1300	Acute Inhalation Toxicity, rat – SXX	46246247	264	OWN	
870.2400	Primary eye irritation, rabbit – JAU	46246248	264	OWN	
870.2400	Primary eye irritation, rabbit – SXX	46246250	264	OWN	
870.2500	Primary dermal irritation, rabbit – JAU	46246307	264	OWN	
870.2500	Primary dermal irritation, rabbit – SXX	46246251	264	OWN	
870.2600	Skin sensitization, guinea pig – SXX	46246308	264	OWN	

Signature: [signature] Name and Title: Melvin K. Fowler, Regulatory Product Manager, Fungicides Date: March 31, 2019

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824	Page: 26 of 36
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Skin sensitization, guinea pig - JAU	46246305	264	OWN	
870.2600	Skin sensitization, guinea pig – JAU des-chloro	46246307	264	OWN	
870.2600	Skin sensitization, guinea pig 1-Chloro-2,4-dinitrobenze	46246308	264	OWN	
870.3100	90-day oral toxicity rat - SXX	46246309	264	OWN	
870.3100	Rodent Range-finding study - SXX	46246310	264	OWN	
870.3100	90-day oral toxicity rat – JAU	46246311	264	OWN	
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020410	264	OWN	
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020403	264	OWN	
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020407	264	OWN	
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020408	264	OWN	
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020405	264	OWN	
870.SUPP	Supplemental study for 90-day oral toxicity rat – JAU	48020406	264	OWN	
870.3100	90-day oral toxicity rat – JAU sulfonic acid K salt	46246312	264	OWN	
870.3150	90-day feeding study dog – JAU	46246313	264	OWN	
870.3150	90-day feeding study dog - SXX	46246314	264	OWN	
870.3200	21day dermal toxicity - JAU	46246315	264	OWN	
870.3700	Developmental toxicity rat - JAU	46246316	264	OWN	

Signature: *Melvin K. Tolliver*	Name and Title: Melvin K. Tolliver, Registration Project Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2016	EPA Reg. No./File Symbol: 264-824 Page: 1 of 26
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709
	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3700	Developmental toxicity rat – JAU pre-chlor	46246317	264	OWN	
870.3700	Developmental toxicity rat – JAU sulfonic acid K salt	46246318	264	OWN	
870.3700	Developmental toxicity rat – SXX	46246319	264	OWN	
870.3700	Developmental toxicity rat – SXY	46246320	264	OWN	
870.3700	Developmental toxicity rat – SXZ	46246321	264	OWN	
870.3700	Developmental toxicity rat – SXY	46246322	264	OWN	
870.3700	Developmental dermal toxicity rat – JAU	46246323	264	OWN	
870.3700	Developmental toxicity rat – JAU sulfonic acid K salt	46246324	264	OWN	
870.3700	Developmental dermal toxicity rat – SXX	46246325	264	OWN	
870.3700	Developmental dermal toxicity rat – SXY	46246326	264	OWN	
870.3700	Supplemental pre-natal developmental toxicity rat	46626801	264	OWN	
870.3700	Developmental oral toxicity rabbit – SXX	46246327	264	OWN	
870.3700	Developmental toxicity rabbit – JAU	46246328	264	OWN	
870.3700	Developmental dermal toxicity rabbit – SXX	46246329	264	OWN	
870.3700	Developmental toxicity rabbit – JAU	46246330	264	OWN	
870.3800	Reproduction/fertility rat – JAU	46246331	264	OWN	
870.3800	Reproduction/fertility rat – SXX	46246332	264	OWN	

Signature: Melanie K. Toliver

Name and Title: Melanie K. Toliver, Regulation Product Manager Fungicides

Date: March 31, 2016

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-[illegible] — Page: [illegible]
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3800	Reproduction/fertility rat – SXX	46246333	264	OWN	
870.3800	Reproduction/fertility rat – JAU	46246334	264	OWN	
870.4100	Rat chronic – JAU	46246335	264	OWN	
870.4100	Dog chronic – JAU	46246336	264	OWN	
870.4100	Dog chronic – SXX	46246337	264	OWN	
870.4200	Carcinogenicity rat – JAU	46246338	264	OWN	
870.4200	Carcinogenicity mouse – JAU	46246339	264	OWN	
870.4200	Carcinogenicity mouse – SXX	46246340	264	OWN	
870.4200	Carcinogenicity mouse – SXX	46246341	264	OWN	
870.4300	Chronic toxicity/carcinogenicity rat – SXX	46246342	264	OWN	
870.5100	Gene mutation, Ames – JAU	46246343	264	OWN	
870.5100	Gene mutation, Ames – SXX	46246344	264	OWN	
870.5100	Gene mutation, Ames – JAU des-chloro	46246345	264	OWN	
870.5100	Gene mutation, Ames – JAU-methyl	46246346	264	OWN	
870.5100	Gene mutation, Ames – JAU-asymmetric isomer	46246347	264	OWN	
870.5100	Gene mutation, Ames – JAU-asymmetric disulfide	46246348	264	OWN	
870.5100	Gene mutation, Ames – JAU-alpha-hydroxy-desthio	46246349	264	OWN	

Signature: *Melvin K. Tollner*	Name and Title: Melvin K. Tollner, Registration Product Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010 | EPA Reg. No./File Symbol: 264-824 | Page: 19 of 2[illegible]

Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709

Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Gene mutation, Ames – JAU-triazolinone	46246350	264	OWN	
870.5100	Gene mutation, Ames – JAU alpha-acetoxy-desthio	46246401	264	OWN	
870.5100	Gene mutation, Ames – JAU sulfonic acid K salt	46246402	264	OWN	
870.5100	Gene mutation, Ames - JAU benzylpropyldiol	46246403	264	OWN	
870.5300	Cell Gene mutation – JAU	46246404	264	OWN	
870.5300	Cell Gene mutation – SXX	46246405	264	OWN	
870.5375	Chromosome aberration test – JAU	46246406	264	OWN	
870.5375	Chromosome aberration test – SXX	46246407	264	OWN	
870.5375	Chromosome aberration test – JAU des-chloro	46246408	264	OWN	
870.5395	Micronucleus Test – JAU	46246409	264	OWN	
870.5395	Micronucleus Test – SXX	46246410	264	OWN	
870.5395	Micronucleus Test – JAU	46246411	264	OWN	
870.5550	Unscheduled DNA Synthesis – JAU	46246412	264	OWN	
870.5550	Unscheduled DNA Synthesis – JAU	46246413	264	OWN	
870.5550	Unscheduled DNA Synthesis – SXX	46246414	264	OWN	
870.5550	Inhibition of cytochrome – JAU	46246415	264	OWN	
870.6200	Subchronic neurotoxicity screen rat – JAU	46246416	264	OWN	

Signature: *Melvin K. Tolliver* | Name and Title: Melvin K. Tolliver, Registration Product Manager, Fungicides | Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-[illegible]	Page: 1 of 3
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione; CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6200	Acute neurotoxicity screen rat – JAU	46245917	264	OWN	
870.6200	Developmental Neurotoxicity Screen rat – SXX	46245918	264	OWN	
870.6200	Developmental Neurotoxicity Screen rat – SXX – brain morphometric data	47253901	264	OWN	
870.7485	Metabolism rat – JAU	46246419	264	OWN	
870.7485	Metabolism rat – SXX	46246420	264	OWN	
870.7485	Metabolism rat – JAU triazole & phenyl label	46246421	264	OWN	
870.7485	Metabolism rat – SXX pilot	46246422	264	OWN	
870.7600	Dermal penetration monkeys – JAU	46246423	264	OWN	
870.7600	Dermal penetration monkeys – SXX	46246424	264	OWN	
870.7600	Dermal penetration monkeys – SXX in SC 480	46246425	264	OWN	
870.7600	Dermal penetration monkeys – JAU 250 EC pilot	46246426	264	OWN	
870.7800	Immunotoxicity – Waiver Request	46024401	264	OWN	
870.None	Range-finding study in CD-1 mice – JAU	46246427	264	OWN	
870.None	Subacute oral, rat – JAU	46246428	264	OWN	
870.None	Subacute oral, rat – JAU	46246429	264	OWN	
870.None	Subacute oral, rat – SXX	46246430	264	OWN	

Signature: Melvin K. Tolliver	Name and Title: Melvin K. Tolliver, Regulatory Project Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010		EPA Reg. No./File Symbol: 264-824
Applicant (Registrant) Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide

Ingredient: (+/-)-trans-alpha-(2-[(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No. 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.None	Subacute oral, dog - SXX	46246431	264	OWN	
870.None	Subacute inhalation, rat - SXX	46246432	264	OWN	
870.None	Subacute inhalation, rat - SXX	46246433	264	OWN	
870.None	Acute intraperitoneal - SXX	46246434	264	OWN	
870.None	Mechanistic subchronic oral - JAU	46246435	264	OWN	
870.None	Thyroid peroxidase-catalyzed reactions - JAU	46246436	264	OWN	
870.None	Liver foci test - SXX	46246437	264	OWN	
870.None	Plaque-forming cell assay in mice - JAU	46246438	264	OWN	
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46020408	264	OWN	
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46020402	264	OWN	
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46020404	264	OWN	
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46020306	264	OWN	
870.SUPP	Sup. study for plaque-forming cell assay in mice - JAU	46020201	264	OWN	
870.None	Plasma kinetics - SXX	46246439	264	OWN	
870.None	Analytical LC method for dose determinations - JAU	46246440	264	OWN	
870.None	Assessment of ovarian findings in rodents - SXX	46246441	264	OWN	

Signature:	Name and Title: Mary E. Tolmer, Registration Product Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010	EPA Reg. No./File Symbol: 264-824	Page 26 of 2[illegible]
Applicant's/Registrant's Name & Address: Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, CAS No.: 178928-70-6		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.None	Validation of the Magnusson-Kligman Maximization Test Method	46246842	264	OWN	
870.None	Validation of the Magnusson-Kligman Maximization Test Method	46246843	264	OWN	
870.None	Analytical-LC method in rodent rations - SXX	46246844	264	OWN	
870.None	Tier II Summaries for Toxicology Studies	46246845	264	OWN	
Occupational & Residential Exposure					
875.2100	Foliar dislodgeable residue	46979102	264	OWN	
875.2100	Foliar dislodgeable residue	47802601	264	OWN	
875.2100	Foliar dislodgeable residue	47623601	264	OWN	
875.Group A and B	Occupational Exposure and Safety Assessment for Prothioconazole	46246846	264	OWN	
875.Group A and B	Assessment of Non-Dietary Exposure on sweet, pop, and field corn	47501904	264	OWN	
875.None	Determination of Exposure to JAU 6476 & JAU 6476 desthio (SXX0665) During Mixing/Loading & Application of JAU 6476 in Cereals	46246847	264	OWN	
875.None	Determination of Exposure to JAU 6476 & JAU 6476 desthio (SXX0665) During Mixing/Loading & Application of JAU 6476 in Cereals -- Raw Data	47737401	264	OWN	

Signature: *Melvin K. Tolliver*	Name and Title: Melvin K. Tolliver, Registration Product Manager, Fungicides	Date: March 31, 2010

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DATA MATRIX

Date: March 31, 2010		EPA Reg. No./File Symbol: 264-824	Page [illegible] of 39
Applicant's/Registrant's Name & Address:	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	

Ingredient: Prothioconazole, 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione CAS No.: 178928-70-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.None	Tier II Summaries for Occupational and Residential Exposure	46246443	264	OWN	
1,2,4-Triazole and Derivatives		Cite-all	US Triazole Task Force	Member	
Spray Drift Data Requirements		Cite-all	Spray Drift Task Force	Member	
Reentry Data Requirements					
875 Group B	Residential exposure	Cite-all	Outdoor Residential Exposure Task Force	Member	
875 Group B	Reentry exposure	Cite-all	Agricultural Reentry Task Force	Member	
875 Group A	Handler exposure data	Cite-all	Agricultural Handlers Exposure Task Force	Member	

Signature: Melvin K. Tolliver	Name and Title: Melvin K. Tolliver, Registration Product Manager, Fungicides	Date: March 31, 2010

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Date: March 31, 2010		EPA Reg. No./File Symbol: 264-824	Page 2 of 2
Applicant's/Registrant's Name & Address	Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709	Product: Prothioconazole Technical Fungicide	
Ingredient: Prothioconazole: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione; CAS No. 178928-70-6			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Miscellaneous					
None	Tier III Summaries, Prothioconazole	46246548	264	OWN	
None	Public Interest Document	46765301	264	OWN	

Signature	Name and Title	Date
Melvin K. Tolliver	Melvin K. Tolliver, Registration Product Manager, Fungicides	March 31, 2010